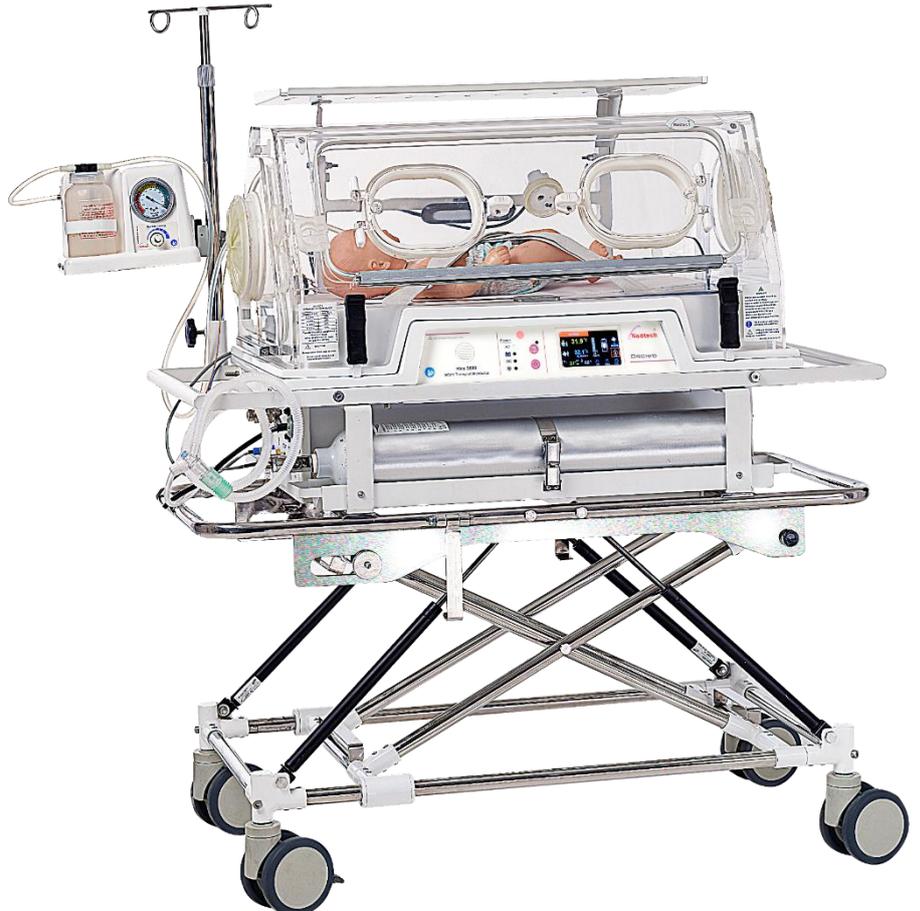


Infant Transport Incubator with TFT Display, Servo Skin and Servo Air

nice 3000 User manual

This user manual provides all the information necessary for the user to safely set up and operate this equipment.

It is the responsibility of the user to follow the instructions and recommendations provided.



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User Responsibility / Operator Profile

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. Operator is positioned near to the front panel of the device. The device should be placed leaving sufficient from the wall to access/disconnect the device backside easily. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately, should such repair or replacement become necessary, nice Neötech recommends that a telephone or written request for service advice be made to the nearest nice Neötech Regional Service Center.

This Product or any of its parts should not be repaired other than in accordance with written instructions provided by nice Neötech and by nice Neötech trained personnel. The Product must not be altered without the prior written approval of nice Neötech's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than nice Neötech.

While switching off the infant transport incubator, switch off the power at control box and then the Main power and disconnect the power cord.



Warning

- Before using the nice Neötech Infant Transport Incubator, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the benefits and risks of this type of device.

Declaration for Languages

User Manual and label will be provided in the appropriate language to ensure that the user understands. Language validation will be done for the language of the user manual, Label, Corresponding documents, when nice Neötech Medical Systems Private Limited supplies to EU countries

Declaration for RoHS

RoHS electronic components are used for production of the devices and complies with Annex I categories of the RoHS Directive 2011 / 65 EU

Model Descriptions

nice 3000 Orchid provide a servo-controlled source of air and servo skin with non-servo Oxygen and Humidity for neonates and infants. The control system uses a microprocessor and provides servo air mode and servo baby mode of operation. nice 3000 is a superior model, designed with all features and has TFT touch display.

Definitions

- a. **Infant Transport Incubator Temperature:** Air temperature at a point 10 cm (3.9 in) above and centered over the mattress surface.
- b. **Control Temperature:** The Temperature Controller's Set Point Selected by User.
- c. **Average Infant Transport Incubator Temperature:** The average of the maximum and minimum Infant Transport Incubator Temperature achieved during **Temperature Equilibrium**.
- d. **Infant Transport Incubator Temperature Equilibrium:** The condition reached when the average **Infant Transport Incubator Temperature** does not vary more than 1.0°C over the period of one hour. These measurements are taken at **control temperatures** of 32°C and 36°C.
- e. **Temperature uniformity:** The amount by which the average temperature at each of four points 10 cm (4 in.) above the mattress surface differs from the **Average Infant Transport Incubator temperature** at Infant Transport Incubator Temperature Equilibrium.
- f. **Temperature Variability:** The Variability of the Infant Transport Incubator Temperature that will be observed over a one hour period after Infant Transport Incubator Temperature Equilibrium has been reached.
- g. **Temperature rise time:** The time required for the Infant Transport Incubator Temperature to rise 11°C, when the air Control Temperature is at least 12°C above ambient.
- h. **Temperature Overshoot:** The amount by which Infant Transport Incubator Temperature exceeds Average Infant Transport Incubator Temperature at Infant Transport Incubator Temperature Equilibrium shall be restored within 15 minutes as a result of an increase in Control Temperature Value.
- i. **Temperature Correlation:** Temperature indicator Vs. Infant Transport Incubator Temperature, the amount the air temperature Indicator at Infant Transport Incubator Temperature Equilibrium differs from the Infant Transport Incubator Temperature.
- j. **Measurement Points:** Measurements are taken at five points in a plane parallel to and 10 cm above the mattress surface. One point shall be 10 cm above the centre of the mattress; the remaining four points shall be the centers of four areas formed by lines, which divide both the width and length in two parts.

Definition of Warning indication

Three levels of Warning indication are used throughout this manual and on the unit. They are defined as follows;

A **DANGER** notice indicates an immediately hazardous situation which, if not avoided, will result in death or serious injury, serious damage to property such as total loss of use of equipment, and a fire.

A **WARNING** notice indicates an indirectly (Potentially) hazardous situation which if not avoided, will result in death or Serious injury, serious damage to property such as total loss of use of equipment, and a fire.

A **CAUTION** notice indicates a hazardous situation which, if not avoided can result in minor or moderate injury, partial damage to property and loss of data stored in computers.

Hazards of Infant Transport Incubator

The Infant Transport Incubator cannot differentiate between an increase in core temperature with cold skin (fever), and low core and skin temperature (hypothermia). Patient temperature should be verified with an ancillary thermometer.

Skin temperature probe which are applied to operate Infant transport incubator including the displayed value are considered to be not a clinical thermometer.

A patient placed in any Infant Transport Incubator will normally develop temperature gradients with hotter and cooler areas. This is due to radiant heat being applied above the infant, the unequal skin cooling effect from evaporative water loss, unequal heat generation within the patient, and the environmental variables of room temperature, room air movement, incidental sunlight, etc.

Section A: Warnings



- Infant Transport Incubator is intended for use by a qualified practitioner under the direction of qualified physician. Personnel operating the Infant Transport Incubator must become thoroughly familiar with the instruction manual prior to using the Infant Transport Incubator with the patients.
- To avoid the risk of electric shock, Infant Transport Incubator must only be connected to a supply mains with protective earth.
- Only facility-authorized personnel should troubleshoot the model nice 3000 Infant Transport Incubator. Troubleshooting by unauthorized personnel could result in Personal injury or equipment damage.
- Do not use the Infant Transport Incubator if it fails to function as described. Personal injury or equipment damage could occur. Refer the unit for servicing by qualified personnel.
- To prevent Personal injury, Particular care must be taken to ensure that the additional Equipment connected to the baby is electrically safe.
- A dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide built-up. Check the filter once in 15 days and change it at least every 3 months or when it is visibly dirty. Failure to do so could result in infant injury.
- Allow 45 minutes for the heater assembly to cool. Failure to do so could result in personal injury.
- Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.
- Make sure that the oxygen supply to the Infant Transport Incubator is turned off and that the Infant Transport Incubator is disconnected from the oxygen supply when performing cleaning procedures. A fire and explosion hazard when cleaning in an oxygen-enriched environment.
- nice 3000 dose not having any additional Equipment to maintain the hood Temperature.
- Failure to clean the heater radiator and fan impeller could result in sufficient lint built-up to reduce airflow, which will affect temperature control and cause high oxygen concentrations. Infant injury could occur.
- Only facility-authorized personnel should perform preventive maintenance on the model nice 3000 Infant Transport Incubator. Preventive maintenance performed by unauthorized personnel could result in personal injury or equipment damage.
- To keep the Infant Transport Incubator from sliding when parked on an incline, the trolley's casters must be locked.
- Oxygen Flow rates cannot be used as an accurate indication of oxygen concentration in Infant Transport Incubator. Continuously monitor the oxygen concentrations with a calibrated oxygen analyzer. Failure to do so could result in Personal injury.
- Ensure all sensor leads are properly routed. Use cable management clips to avoid entanglement and possible infant injury.
- The use of oxygen increases the danger of fire and the auxiliary equipment producing spark shall not be placed in the equipment, even Small quantity of flammable agents such as ether and alcohol, left in the Infant Transport Incubator it can cause fire in connection with oxygen
- The direct sun light or other radiant heat sources can cause an increase in Infant Transport Incubator temperature to dangerous levels

- The warm up time of the Infant Transport Incubator is less than 45 minutes to attain the temperature of 32°C in the baby compartment
- The administration of oxygen may increase the noise level for the baby within the Infant Transport Incubator.
- The nice 3000 should not be used near active high-frequency equipment, MRI machines, high-frequency ventilators, defibrillators or strong RF sources such as mobile phones and wireless communication systems. Exposure to high electromagnetic disturbances may cause inaccurate monitoring, unexpected device behavior, or malfunction. Proper shielding and there must be a separation distance of at least 1.0m (3.3 ft) between this device and wireless communication device/ systems.
- The nice 3000 should not be used adjacent to or stacked with other equipment, as this may lead to improper operation. If such use is unavoidable, both the nice 3000 and the other equipment must be carefully monitored to ensure they are functioning correctly. Failure to do so may result in device malfunction, inaccurate performance, or potential safety risks.
- The nice 3000 is a Class A equipment (CISPR 11, Group 1 Classification) make it suitable for use in hospitals. Use in a residential environment may cause radio-frequency interference, as CISPR 11 Class B is normally required for such settings. To prevent potential disruptions to communication services, users should take mitigation measures, such as relocating or re-orienting the equipment if interference occurs.
- Use of nice Neotech cables only. Use of cables other than those specified or provided by the nice Neotech of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The Infant Transport Incubator may cause radio interference, in which case adequate measure may be required to prevent interference
- nice 3000 Infant Transport Incubator compliance with EN/IEC 60601-1-2, the use of accessories, sensors and cables other than specified may result in increased emission/or create invalid output of nice 3000
- Do not use skin temperature sensor in rectum, rectal temperatures must never be used to skin control patient's temperature.
- Disconnect the battery terminal from the Infant Transport Incubator is not to be used some time, the battery may get leakage could cause unacceptable risk.
- Battery should be replaced only by the trained service personnel.
- Do not perform the service or maintenance activity while in use with the patient in infant Transport Incubator.
- Verify the duration of power backup periodically in fully usable condition, the battery backup may reduce due to long cycle of usage.

Shock Hazard: Ensure that the building power source is compatible with the electrical specifications shown on the left side of the Infant Transport Incubator. For proper grounding reliability, connect the power cord only to a properly marked, three-wire, hospital-grade or hospital-use receptacle. Do not use extension cords.

Shock Hazard: Unplug the power cord from the controller assembly. Failure to do so could result in Personal injury or equipment damage.

Shock Hazard: Do not expose the unit to extensive moisture. Personal injury or equipment damage may occur.

Section B: Cautions



- Connect the sensor cable to the corresponding sensor connector only. Do not connect the sensor cable to any other connector.
- Do not use harsh cleansers, such as scouring pads or heavy-duty grease removers or solvents, such as acetone. Equipment damage could occur.
- Some chemical cleaning agents may be conductive and/or leave a residue that may enable a built-up of conductive dust or dirt. Do not permit cleaning agents to contact electrical components. Do not spray cleaning solutions onto any of these surfaces. Equipment damage could occur.
- Do not use alcohol for cleaning. Alcohol can cause crazing of the clear acrylic hood.
- Do not hide or block the Alarm sound way on the heater module. It may reduce or nullify the alarm sound.
- Do not expose the hood assembly to direct radiation from germicidal lamps. Ultraviolet radiation from these sources can cause cracking of gaskets, fading of paint, and crazing of the clear acrylic hood.
- To prevent Component damage, ensure that your hands are clean, and only handle the P.C. board by its edges.
- When handling electronic components wear an antistatic strap Failure to do so could result in component damage.
- For shipping and Storage Place the removed P.C. board in an antistatic protective bag Equipment damage could occur.
- Do not use silicone-based lubricants. Equipment damage could occur.
- When removing the equipment from the cartons, take care not to scratch or otherwise damage unprotected surfaces.
- Before lifting the Infant Transport Incubator hood for cleaning, ensure that all mounted accessories have been removed to prevent possible interference with the raised hood.
- To avoid Equipment damage, use only distilled or sterile water. Sterile water alone is not an acceptable substitute for distilled water.
- Isolation from the supply mains is by removing the plug because non detachable Power cord is provided.
- The equipment may show incorrect reading while using the defibrillator.
- Periodically clean and disinfect the Infant Transport Incubator it fails cause cross infection
- Do not use the equipment in the presence of flammable agents

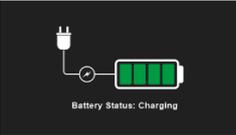
Use of nonstandard components: Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

Attention: nice 3000 is not intended to Produce X Radiation for diagnostic and therapeutic purposes.

Section C: Symbols and Labels

Mark	Title
Manufacturer	
	Manufacturer – Indicates the medical device manufacturer
	Date of Manufacture – Indicates the date when the medical device was manufactured.
	Country of manufacture – To identify the country of manufacture of products.
	Authorized representative in the European Community/ European Union – Indicates the authorized representative in the European Community/ European Union
	Catalogue number – Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial Number – Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Batch code – Indicates the manufacturer's batch code so that the batch or lot can be identified.
	CE Mark European Conformity - Signifies European conformity (CE) mark Indicates manufacturer declaration that the product complies with applicable European regulations.
Sterility	
	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged and consult IFU - Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
Storage	
	Fragile, handle with care - Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry - Indicates a medical device that needs to be protected from moisture.
	Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation - Indicates the range of humidity to which the medical device can be safely exposed.

	Do not keep near fire – Do not keep the package near fire
	Maximum stackable limit – Pay attention to numbers on the stacked boxes icon. Some stacks will have top boxes marked with an X (number)
	This way up – For the duration/ delivery, the carton should face upright.
Safe use	
	Warning - indicates an indirectly (Potentially) hazardous situation which if not avoided, will result in death or Serious injury, serious damage to property such as total loss of use of equipment, and a fire.
	Caution - Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Refer Instruction for use – Indicates the need for the user to refer instructions for use given by the manufacturer
	Consult instructions for use or consult electronic instructions for use - Indicates the need for the user to consult the instructions for use.
On Device	
	General Prohibition sign
	Do not step on surface
	Use no oil
	General mandatory action
	Alternating current
	Direct Current
	Off (Power: disconnection from main)
	On (Power: connection to the main)
	Type BF Equipment
	Type B (Mattress)

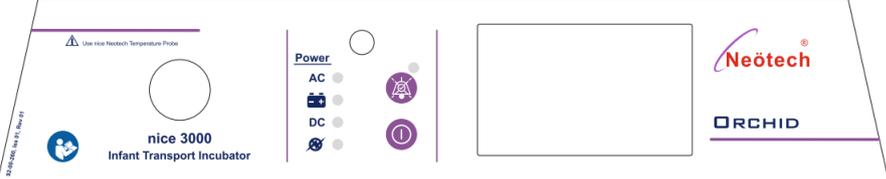
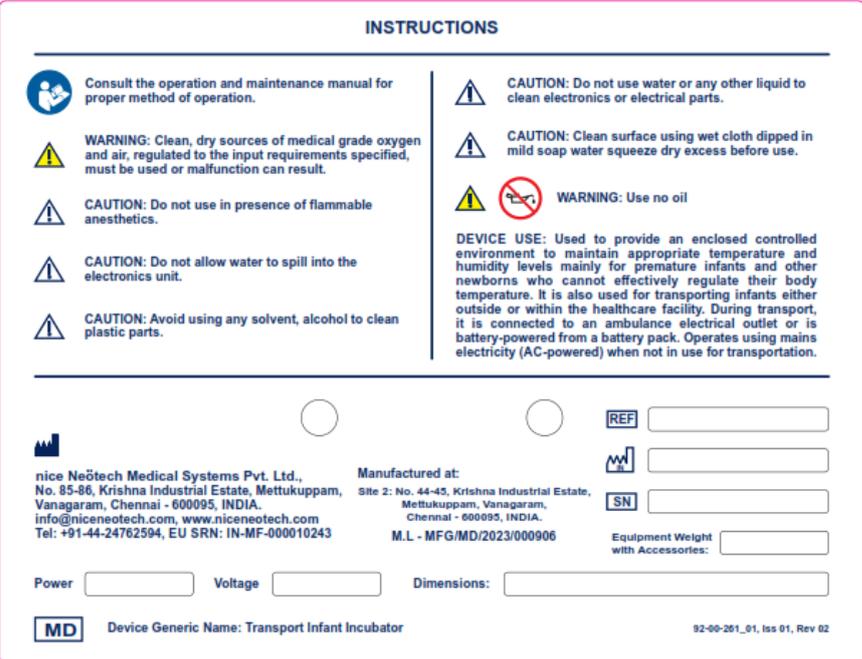
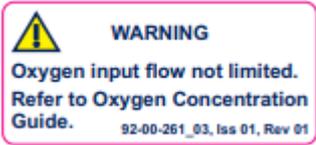
	ON/OFF key
	Timed Acknowledged key
AC	AC Power
DC	DC Power
	Main switch
	Battery
	Power failure
	Skin temperature sensors
	Battery Charging Status
	Battery Power Status
	AC Power
	External DC
	Skin temperature

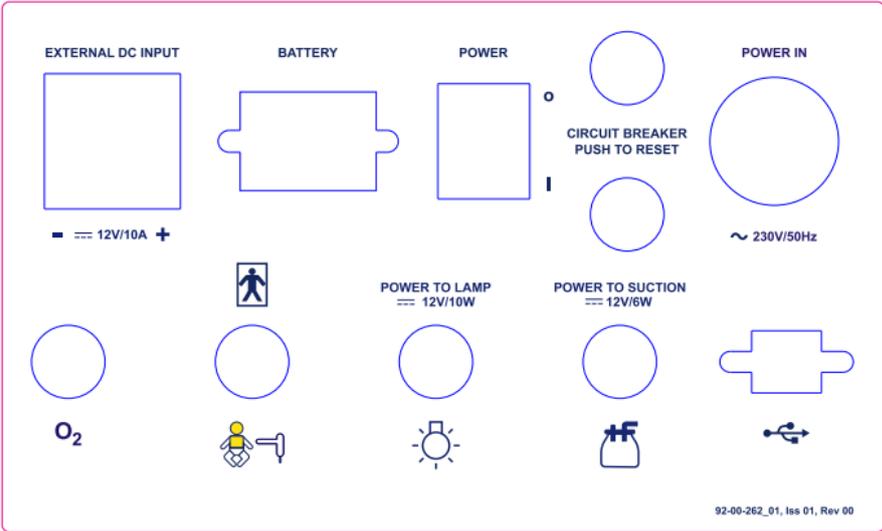
	Air temperature
	Heater Output
	Suction
	Baby Mode
	Air Mode
	Stand By
	Observation Lamp
	Unlock
	Lock
	Settings
	Humidity
	Oxygen Percentage
	OK
	Cancel

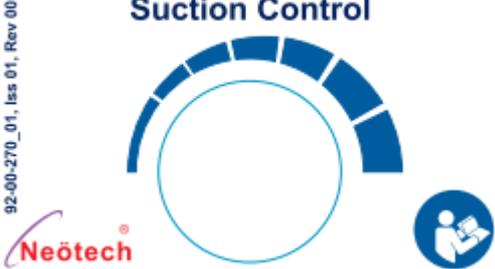
	Save
	Defaults
	Start
	Stop
	Factory Default
	Decrease Key
	Increase Key
	Max weight 1.5kg
	Max weight 3kg
Others	
	Medical Device - Indicates the item is a medical device
	Type BF Equipment – Indicates that the applied part is electrically connected to patient but not directly to heart.
	WEEE Complaint - The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.
	Recyclable Package – The product can be recycled or it was made from recycled materials.
	Phthalate free – Indicates that the product does not contain the phthalate plasticizers DEHP, BBP and DBP.
	Indicates the absence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device

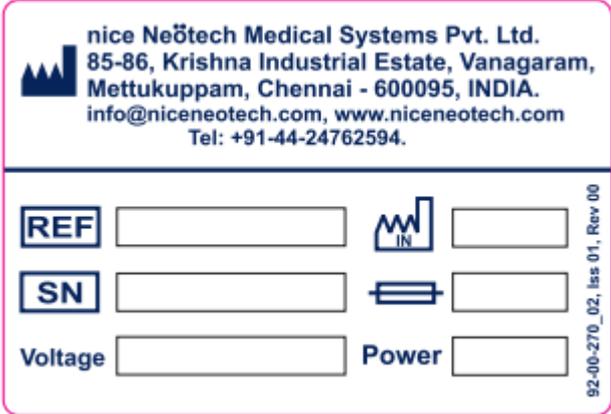
	<p>Use trolley for transportation – Used for heavy products that are difficult to carry by hand, even if you have multiple people.</p>
	<p>RoHS Complaint – RoHS (Restriction of Hazardous Substances) Indicates that no hazardous substances have been used in the product</p>
	<p>Unique device identifier - Indicates a carrier that contains unique device identifier information</p>

Labels

S. No	Label	Part Number	Label Description
1.		92-00-260	Label – nice 3000 Front Panel
2.		92-00-261_01	Label – Name Plate
3.		92-00-261_02	Label – Air filter
4.		92-00-261_03	Label – Warning
5.		92-00-261_04	CE Label

6.	 <p>92-00-261, Iss 01, Rev 02</p>	92-00-261	O2 Cylinder
7.	 <p>92-00-262_01, Iss 01, Rev 00</p>	92-00-262_01	Label – Power supply
8.	 <p>REF 87-00-126/87-00-139/87-00-008/87-00-009 - Mattress</p> <p>Caution Before using the mattress clean with cloth damped with soft soap water. Cover the mattress with cloth before placing the baby. Don't Clean the mattress with hard brush. it may damage. Mattress are only cleaned with soft cloth and packed in the process, not sterilized or disinfected.</p> <p>Warning Do not immerse the mattress in any kind of liquid. This will cause damage to the mattress and will void the warranty.</p> <p>Ph.: +91-44-24762594, www.niceneotech.com</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">92-00-239_01, Iss 01, Rev 02</p>	92-00-239	Label - Mattress

9.	<div data-bbox="485 237 828 752" style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;">OXYGEN CONCENTRATION GUIDE</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Oxygen Input</th> <th style="text-align: left;">Hood O₂ %</th> </tr> </thead> <tbody> <tr> <td>2 L/min</td> <td>25%</td> </tr> <tr> <td>4 L/min</td> <td>30%</td> </tr> <tr> <td>6 L/min</td> <td>40%</td> </tr> <tr> <td>8 L/min</td> <td>50%</td> </tr> </tbody> </table> <p>Figures should be considered nominal values Allow 40 minutes for hood oxygen to stabilize.</p> <p> CAUTION</p> <p>Do not clean hood with alcohol. Do not use in presence of flammable anesthetics.</p> <p style="font-size: small; text-align: right;">92-00-262_02, Iss 01, Rev 00</p> </div>	Oxygen Input	Hood O ₂ %	2 L/min	25%	4 L/min	30%	6 L/min	40%	8 L/min	50%	92-00-262_02	Label – Oxygen concentration guide
Oxygen Input	Hood O ₂ %												
2 L/min	25%												
4 L/min	30%												
6 L/min	40%												
8 L/min	50%												
10.	<div data-bbox="485 864 828 1373" style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;"> WARNING</p> <p>Patient temperature should be verified with ancillary thermometer, as infant transport incubator cannot differentiate between an increase in core temperature with cold skin (fever), and low core and skin temperature (hypo-thermia).</p> <p> Tie the Infant with strap, provided with mattress.</p> <p> All hood latches to be locked when operating Incubator.</p> <p>CAUTION</p> <p style="font-size: small; text-align: right;">92-00-262_03, Iss 01, Rev 00</p> </div>	92-00-262_03	Label – Warning										
11.	<div data-bbox="387 1417 922 1736" style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;">Suction Control</p>  <p style="font-size: small; text-align: left;">92-00-270_01, Iss 01, Rev 00</p> </div>	92-00-270_01	*Label – Suction Front panel										

12.	 <p>nice Neotech Medical Systems Pvt. Ltd. 85-86, Krishna Industrial Estate, Vanagaram, Mettukuppam, Chennai - 600095, INDIA. info@niceneotech.com, www.niceneotech.com Tel: +91-44-24762594.</p> <p>REF <input type="text"/>  <input type="text"/></p> <p>SN <input type="text"/>  <input type="text"/></p> <p>Voltage <input type="text"/> Power <input type="text"/></p> <p style="font-size: small;">92-00-270_02, Iss 01, Rev 00</p>	92-00-270_02	*Label-Suction marking plate
13.	 <p style="text-align: center;">Suction Outlet</p> <p style="font-size: x-small; text-align: center;">92-00-270_03, Iss 01, Rev 00</p>	92-00-270_03	*Label-Suction outlet
14.	 <p>Neotech REF <input type="text"/></p> <p>SN <input type="text"/></p> <p>Ph.: +91-44-24762594, www.niceneotech.com</p> <p style="font-size: x-small;">92-00-240, Iss 01, Rev 01</p>	92-00-240	Label – Skin temperature sensor tag
15.	 <p style="text-align: center;">UDI</p> <p style="text-align: center;">(01) 0 8908003 98913 6 (21) ITI230300035</p>	--	UDI Label
16.	 <p style="text-align: center;">MAX 1.5kg</p>	92-00-239	Max weight 1.5kg
17.	 <p style="text-align: center;">MAX 3kg</p>	92-00-239	Max weight 3kg

18.		92-00-239	Safety sign, Do not step on surface
19.		92-00-239	Safety sign, Do not lean on warmer
20.		92-00-239	Safety sign, Hot surface
21.		92-00-002	Neotech Brand logo
22.	<div style="display: flex; justify-content: space-between;"> <div data-bbox="225 1205 647 1621"> <p>nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-600095, India. Tel: +91-44-24762594, Web: www.niceneotech.com</p> <hr/> <p>Product Name Mattress</p> <p>Generic Name Accessory of "Infant Radiant Warmer or Incubator or Transport Incubator"</p> <p>Device use Intended to provide cushion to the Baby placed on the bed platform.</p> <p>Mfg. Lic. No. MFG/MD/2023/000906 <small>*Sold only as a part of device "Infant Radiant Warmer or Incubator or Transport Incubator"</small></p> </div> <div data-bbox="668 1205 1091 1621"> <p>REF 87-00-xxx</p> <p>LOT XXXXXXXXX</p> <p>XXXXXX</p> <p>Dimension in cm XX(L) x XX(W) x XX(H)</p> <p>Weight in kg XX kg</p> <p>No. of units inside XX nos.</p> <p>CE 1434</p> <p>EC REP Amstermed B.V. Saharnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl ; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-00001971</p> </div> </div>	--	Packing label - Mattress

<p>23.</p>	<p>nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-600095, India. Tel: +91-44-24762594, Web: www.niceneotech.com</p> <p>Product Name Skin Temperature Probe</p> <p>Generic Name Accessory of Infant Radiant Warmer or Incubator or Transport Incubator</p> <p>Device use Intended to measure the baby's skin temperature and provide feedback to the control unit of Infant Radiant Warmer or Incubator or Transport Incubator.</p> <p>Mfg. Lic. No. MFG/MD/2023.000906 *Sold only as a part of device Infant Radiant Warmer or Incubator or Transport Incubator*</p>	<p>REF 50-05-239</p> <p>LOT XXXXXXXXX</p> <p>XXXXXX</p> <p>Dimension in cm XX(L) x XX(W) x XX(H)</p> <p>Weight in kg XX kg</p> <p>No. of units inside XX nos.</p> <p>CE 1434</p> <p>Amstermed B.V. Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl ; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-00001971</p>	<p>--</p>	<p>Packing label – Skin Temperature probe</p>
<p>24.</p>	<p>Product Name Infant Transport Incubator</p> <p>Generic Name Transport Infant Incubator</p> <p>Brand Name Orchid</p> <p>Module Final Assembly</p> <p>Device use Intended to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other neonates who cannot effectively regulate their body temperature. It is typically on wheels and also designed for transporting infants either outside or within the healthcare facility.</p> <p>Mfg. Lic. No. MFG/MD/2023.000906</p>	<p>REF nice 3000</p> <p>SN ITYYMMXXXXX</p> <p>24/12/2022</p> <p>UDI 011 0 830003 98913 6 (21) Serial no</p> <p>Dimension in cm: 55(L) x 46(W) x 71(H)</p> <p>Weight in kg: 50 kg</p> <p>No. of units inside: 01 nos.</p> <p>MRP: Rs. 3, 90,000/-</p> <p>nice Neotech Medical Systems Pvt. Ltd., No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India. TEL - +91-44-24762594/24764608 www.niceneotech.com, info@niceneotech.com SRN: IN-MF-000010243</p> <p>Manufactured at: Site 2: No. 44-45, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India.</p> <p>CE 1434</p> <p>Amstermed B.V. Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl ; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-00001971</p>	<p>--</p>	<p>Label – Packaging, Transportati on and storage Instruction</p>

Section 1: Description

- 1.1 Intended Use
- 1.2 Medical Indications/Conditions
- 1.3 Contraindication
- 1.4 Side Effects
- 1.5 Intended Patient Population
- 1.6 Device Intended User
- 1.7 Working Principle
- 1.8 Product Description
- 1.9 UDI Carrier

1.1 Intended Use

The infant Transport Incubator is intended to circulate warmed air at an operator selected and controlled temperature when transporting neonates to hospitals by ambulance, prepared for neonatal intensive care by personnel, trained in neonatal care.

Infant Transport Incubator provide continuous optimum thermal environment for the infant who's are low weight even 600gms and up to 5kgs, high risk and critical condition, less the gestation period of 36 weeks during transport.

1.2 Medical Indication/Conditions

- Transporting the subject with Impairment of vital functions.
- Regulation of heating.

1.3 Contraindication

Severe clinical coagulopathy and major congenital abnormalities.

1.4 Side-effects

Infant Transport Incubator may affect insensible water loss and can also induce rapid drying of the skin surface.

1.5 Intended Patient Population

Premature, Neonates and Infants up to 5 kgs

1.6 Device Intended User

Neonatologist and Healthcare Professionals.

1.7 Working principle

The Infant Transport Incubator provides an optimum thermal environment for the infant in low weight with high risk and less the gestation period of 36 weeks up to 5 kg. The Infant Transport Incubator helps to stabilize the infant's body temperature at the normal level by minimizing the infant's heat loss. The Infant Transport Incubator directs the heated air through the air ducts in it and monitors the inside temperature in it with temperature sensors. The air speed in the Infant Transport Incubator is limited to less than 0.3m/s, thus minimizing the convective heat loss. Fresh heated air is introduced into the Infant Transport Incubator along with reticulated air. The acrylic hood maintains the temperature inside the transport incubator. Three access ports, two large doors, 2 elbow and single Iris port is provided to access the baby during transport and normal use.

1.8 Product Description

nice 3000 Orchid is consist of Infant Transport Incubator with servo-controlled Skin and Air with TFT display.

A fan blows filtered ambient air over a heating element. From the oxygen cylinder additional oxygen can be supplied to the air inside the canopy with the help of flow controller. The heated and oxygen mixed air now flows into the above cabinet with the baby. One part of the air escapes from the cabinet through vent holes, another part gets back into the air processing.

The cabinet is made out of transparent acrylic. A hinged front door can be opened to put the baby in or take it out. Through access panels in the front the nurse has easy access to the baby without letting out the warm air by opening the hood.

After the desired temperature is set by the nurse, it is kept stable automatically by the incubator. The side door helps to access the baby during transport for resuscitation.

Furthermore, the incubator has a safety heater cut-off function when the temperature increases 39°C or reach the required set temperature. Also, an alarm is given when the fan fails, air flow sensor fails, heater fail, skin/air temperature sensor fail/disconnected, low battery and power fail, O2 sensor disconnected, humidity sensor disconnected, Skin temperature high, skin temperature low, Skin over temperature, Air temperature low, air temperature high, air over temperature, oxygen low, Oxygen high.

Two A-type cylinder mounting provision is provided in the lower unit assembly.

Orchid comes with an integrated touch display as a control system built using microcontroller. Patient temperature along with set temperature and non-servo oxygen and humidity functions are controlled and displayed in the TFT display. A complete audio and visual indication system is included on the display panel.

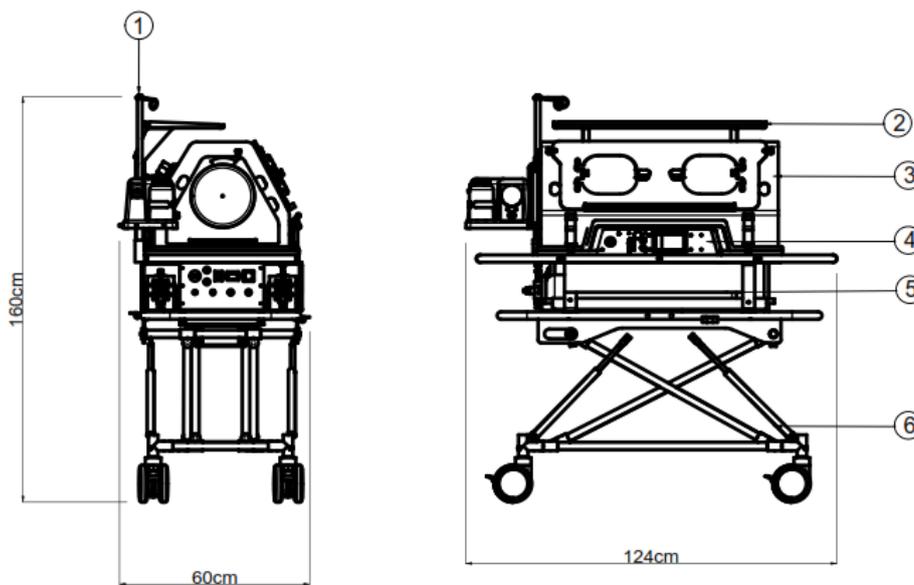


Figure 1

WEIGHT - 115 kgs

nice 3000 Infant Transport Incubator

Sl no.	Part Name
1	IV Pole
2	Auxiliary Tray
3	Hood Assembly
4	Control Unit
5	Power Compartment
6	Trolley Assembly

1.8.1 Fan

The fan takes the filtered room air and blows it over or through the heating element. Without the fan, the heat cannot be conducted away from the heating element and through the heating element and thus the transport

incubator would overheat. To avoid overheat during fan failure, heater will be cut-off through the microcontroller and thermostat.

1.8.2 Filter

Incubators are equipped with disposable filters. It filters the dust particles in intake air.

1.8.3 Heater

A heating element made from silicon called silicon rubber heater pad is used. The power rating is 175 W. The heater is controlled by a microcontroller via a relay, triac, thermistor sensor (to measure the heater temperature) and $90^{\circ}\text{C} \pm 5^{\circ}\text{C}$ thermostat.

1.8.4 Canopy (Hood) Assembly Area

The infant Compartment consists of a double walled, transparent rectangular acrylic hood with hood locker present on all four sides. The hood has a large front door and side door to aid in placing or removing the baby from the incubator. It has 2 elbow operated ports and Iris ports for better access of the infant during small procedures. The hood has inlet for IV tube, Probes and Ventilator tubes.

The control panel is modular, that is the entire TFT display with heater blower and the electronics can be easily replaced in case of repair. This ensures the minimum down time for the equipment.

8.5 Air Circulation

Air is circulated inside the transport incubator using a centrifugal blower. Fresh air enters the incubator air circulation system through the air filters located at the rear end of the incubator. The fresh air is mixed with the circulated air from the incubator canopy is passed over the heater.

The temperature inside the incubator is maintained by a sensor placed on the hood. Thus, the heated air flow maintains the surrounding of the infant at the desired temperature. A slight positive pressure is maintained inside the incubator to prevent any pathogen to enter the incubator through the access ports.

1.8.6 TFT Touch Control Panel

Orchid comes with an integrated TFT touch display control panel to operate infant transport incubator.

The control panel allows the user to access the incubator operations through three modes of operation: Baby mode, Air mode and Standby mode. The transport incubator consists of an infant Compartment (Canopy), Lower unit and trolley. The transport incubator TFT display Control panel is located at the lower unit. The microprocessor-based control system provides a controlled temperature environment for the infant. The TFT display panel visually indicates visual indications on the slots provided in display while an audible indication sounds & visual audio indication to alert the operator to check the condition. The unit also features an over temperature safe system. The patient temperature, the air temperature, Oxygen percentage and humidity percentage are continuously displayed on the TFT displays.

Baby mode:

Baby mode is a servo-controlled operation which automatically controls the radiant heater based on the set required temperature and actual temperature of the baby. Actual temperature of the baby will be recorded by the skin temperature sensor and displayed in the control unit, the information from the sensor is supplied to the heater control unit, which proportions the heater output to maintain the baby set temperature. In baby mode, the control unit enables the user to control the overall Skin Temperature with override function is between 30°C to 39°C . And the skin temperature limit ranges from 30°C to 37.5°C (without override function).

Override Function: If override function is enabled, in ON condition the control temperature can be adjusted from 37.6°C to 39°C . And when disabled, in OFF condition the control temperature can be adjusted only from 30°C to 37.5°C and cannot be exceeded from 37.6°C to 39°C as per the patient response is set by the physician.

Air mode:

Air mode is a servo-controlled operation which automatically controls the heater based on the set required temperature and actual ambient temperature. Actual ambient temperature will be recorded by the air temperature sensor and displayed in the control unit, the information from the sensor is supplied to the heater control unit,

which proportions the heater output to maintain the set temperature. In air mode, the control unit enables the user to control the Air Temperature between 23°C to 39°C.

The Air temperature is measured by the sensor mounted inside the incubator. When the Air Mode of operation is selected, the heater is proportionately controlled to maintain the air temperature at the selected control temperature. The patient sensor may be used to monitor patient skin temperature, but does not control the air temperature in the Skin Mode.

Orchid incubator circulates the humidified air with oxygen into the hood by allowing the air through humidity water chamber and oxygen gas path. Humidity inside the hood is non-servo controlled, the control panel enables the user to check the relative humidity inside the hood. An integrated oxygen flow meter enables the user to set the flow rate of oxygen to mix with the circulated air inside the hood.

Non-servo oxygen system allows the user to set the FiO₂ % limits using the control panel.

Orchid enables the priority of audio and visual indications to alert the doctor/clinician promptly when an error arises or attention is required.

A memory back up system holds the data of Control temperature and the mode of operation even if the power is OFF and is ON again. A battery-operated power failure indication activates when the external power source fails or is disconnected.

Observation lamp with ON/OFF indication with time adjustment is provided in the control panel.

Standby mode:

Standby mode is an operation, to warm the bed platform before the baby is placed on the bed for treatment in which skin and air were not controlled. In Standby mode, the heater will provide 100% heater output after 10 minutes the heater output is reduce to 30% and maintained.

i-sense technology

The i-sense technology in the control panel provides extra safety to the patient during skin temperature sensor being displaced or detached from the patient.

In Baby mode,

1. If the baby Skin Temperature values ranges between 39°C to 42°C and air temperature is <3°C from the Skin Set temperature are continues for 6 minutes, the heater output is reduced to 30%. Function reset condition will be triggered if the air temperature rises above -3°C from the Skin Set temperature.
2. If the heater output is >80% and air temperature is >1°C from the Skin Set temperature are continues for 20 minutes, the heater output is reduced from >80% to 30%. Function reset condition will be triggered if the air temperature reaches <1°C from the Skin Set temperature.
3. If the baby Skin Temperature value is higher than the Skin Set Temperature and air temperature is <3°C from the Skin Set temperature are continues for 6 minutes, the heater output is reduced to 30%. Function reset condition will be triggered if the air temperature reaches above -3°C from the Skin Set temperature

In Air mode,

1. If the baby Skin temperature value ranges between 39°C to 42°C and air temperature is <2°C from the Air set temperature are continues for 6 minutes, the heater output is reduced to 30%. Function reset condition will be triggered if the air temperature rises above -2°C from the Air Set temperature.

1.8.7 Trolley

The Infant Transport Incubator trolley is of tubular and collapsible construction is designed to fit in ICU in place of standard stretcher trolley.

1.8.8 IV Stand

IV Stand is mounted on the left rear side of the Infant Transport Incubator. The Stainless steel pole can support two bottles simultaneously.

1.8.9 Mattress Tray

The Infant Transport Incubator Mattress tray includes a mattress. It can slide out from the hood for procedures of the baby when in transport. The mattress tray has restraining baby strap for securing the baby while transport.

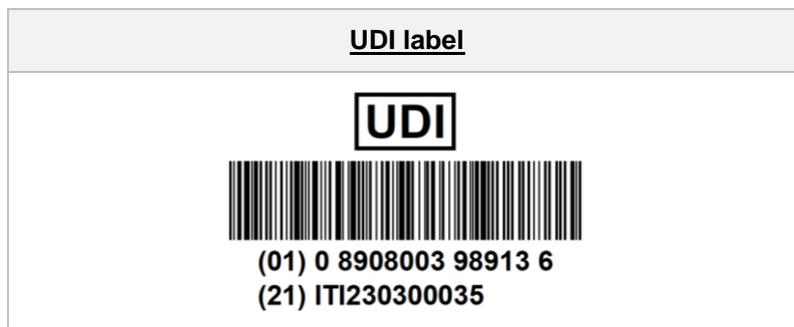
1.8.10 Suction (Optional)

The suction is mounted on the left side of the canopy, suction bottle is placed in the suction bottle holder. Suction removes the blockage or secretions from the baby respiratory tract.

1.9 UDI Carrier

The UDI identifies Infant Transport Incubator with Accessories throughout distribution and product life. The UDI appears on the Infant Transport Incubator with Accessories label and it contains two parts i.e., device identifier (DI) and production identifier (PI). The UDI is established as per the requirements Chapter III and Annex VI of Regulations (EU) 2017/745.

Device Variant	Device Identifier (DI)	Production Identifier (PI)
nice 3000	08908003989136	ITIIYYMMXXXXX (3 digit Product code + YY + MM + 5 digit serial number)



Section 2: Installation

- 2.1 Unpacking and Inspection
- 2.2 Assembling the trolley
- 2.3 Assembling Infant Transport Incubator with trolley
- 2.4 Installation of Canopy (Hood)
- 2.5 Unlock/Lock the trolley
- 2.6 Fixing battery
- 2.7 Fixing the Oxygen Cylinder
- 2.8 Installation of Accessories
- 2.9 Humidity/O₂ Module (Optional)
- 2.10 Installation of Humidity System
- 2.11 Mechanical Checkout Procedure
- 2.12 Controller Checkout Procedure

2.1 Unpacking and Inspection

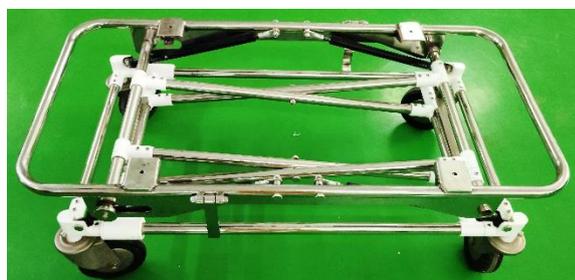
- Remove the equipment from shipping containers and unpack all the assemblies and accessories of Infant Transport Incubator.
- After removal from the shipping containers, inspect the nice Neötech Infant Transport Incubator and all accessory items for any signs of damage which may have occurred during shipment.
- Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

Note: File a damage claim with the shipping carrier if damage is found in any of the assemblies or accessories in the container.



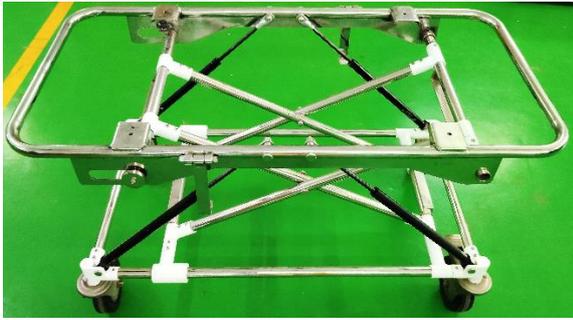
- Do not use the equipment, if damage is found.

2.2 Assembling the trolley



Picture 1

- After removing the trolley from the packing box, lift the trolley to transition it from the collapsed position to the normal position. This involves lifting the sections of trolley until align and lock into place, restoring the trolley to its fully extended.



Picture 2

- Ensure the Trolley is positioned properly as shown in the image.

Note: When lifting the trolley to transition it from the collapsed position to the normal position, at least two persons should handle.

2.3 Assembling Infant Transport Incubator with trolley



Picture 3

- Place the Infant Transport Incubator with the two pins locating on the trolley and tighten the bolt by using 6 mm allen key.



Picture 4

- Place the oxygen cylinder holder as shown in the picture 4.

2.4 Installation of Canopy (Hood)



Picture 5



Picture 6



Picture 7

Picture 5: Place the inner hood in the groove on the shell.

Picture 6: Place the canopy (outer hood) on top of the inner hood.

Picture 7: Lock the canopy with shell using the hood locker as shown in the picture and ensure proper seating of the canopy.

2.5 Unlock/Lock the trolley



Picture 8

- Press downwards to lock the trolley.



Picture 9

- Pull the lock upwards to unlock the trolley.

2.6 Fixing battery



Picture 10

- To fix the battery, begin by detaching the power compartment panel. Unscrew it carefully to access the battery compartment. Once the panel is removed, securely fix the battery connection into place, ensuring proper alignment and connection as shown in the picture

2.7 Fixing the Oxygen Cylinder



Picture 11



Picture 12



Picture 13

Picture 11: Insert the cylinder in to the bracket.

Picture 12: Press the clip downwards to lock and ensure to tighten the bolt for placing the cylinder firmly at the correct position.

Picture 13: Ensure the cylinder neck should be opposite side of the battery compartment panel.

2.8 Installation of Accessories

2.8.1 Installation of the IV Stand

2.8.1.1 Installation of IV Pole



Picture 14



Picture 15

Picture 14 & 15: Fix the IV pole stand with the holder and tighten the knob.

2.8.1.2 Installation of IV Infusion Rod



Picture 16

- Fix the IV infusion rod with the holder and tighten the knob.



Warning

- Make sure that the oxygen supply to the Infant Transport Incubator is turned off and that the Infant Transport Incubator is disconnected from the oxygen supply when performing cleaning procedures. A fire and explosion hazard when cleaning in an oxygen-enriched environment.

- The use of oxygen increases the danger of fire and the auxiliary equipment producing spark shall not be placed in the equipment.
- Small quantity of flammable agents such as ether and alcohol if left in the Infant Transport Incubator can cause fire in connection with oxygen.
- The administration of oxygen may increase the noise level for the baby within the Infant Transport Incubator.
- Oxygen Flow rates cannot be used as an accurate indication of oxygen concentration in an Infant Transport Incubator. Continuously monitor the oxygen concentration with a calibrated oxygen analyzer. Failure to do so could result in Personal injury or equipment damage.

2.8.2 Installation of Suction (Optional)



Picture 17

- Fix the suction module pole and tighten the knob. Inserting the stand into the designated slot or holder and then turning the knob firmly to secure it in place.



Picture 18
(Front view)



Picture 19
(Back view)

- Place the suction as shown in the image and tight the knob.
- Ensure the knob is tighten.



Picture 20

- Power to suction is connected by 6 pin connector as shown in the image

2.9 Humidity/O₂ Module (Optional)



Picture 21



Picture 22

Picture 20 & 21: Locate the slot in the canopy of the Hood Assembly the module to be inserted. Position the module so that it aligns with the slot on the back side of the canopy. Gently insert the module into the slot, ensuring that it fits.



Picture 23

- Connect the sensor module probe to the power compartment as shown in the image.

2.10 Installation of Humidity System

IMPORTANT: TO PROLONG THE USEFUL LIFE OF THE HUMIDITY MODULE, USE ONLY DISTILLED WATER. STERILE WATER IS NOT AN ACCEPTABLE SUBSTITUTE FOR DISTILLED WATER.



Picture 24

- Open the side access door of the hood
- Pull out the mattress tray from the lower unit.
- Pour the distilled water of 450ml over the sponge being placed at the sponge compartment to making it wet for humidification process.

2.11 Mechanical Checkout Procedure



Warning

- Before using the nice Neotech Infant Transport Incubator, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- Do not perform the Checkout Procedures (Mechanical and Control Unit) while a patient occupies the Infant Transport Incubator.
- Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the Infant Transport Incubator fails any portion of the checkout procedures it must be removed from use and repaired.

2.11.1 Overall Appearance

- Disconnect the power cord from the AC power source for the mechanical checks portion of this procedure.
- Check the overall appearance of the Infant Transport Incubator. There should be no obvious damage.

Setup and Checkout Procedures

- For units with castors, check that all castors are in firm contact with the floor and that the Infant Transport Incubator is stable and moves freely.
- Lock the two front castors and check that the Infant Transport Incubator is held in place.
- Examine the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced by only the trained service personnel.



Warning

- Do not place any accessories or other objects directly over the bed surface. This may block heat energy and lead to cooling of the infant.
- Do not place items on top of the Hood assembly. Items placed on top of the Hood assembly can fall and injure the patient and may pose a fire hazard.

2.11.2 Mechanical Checks

1. Mattress Sliding



Picture 25

- ❖ Open the side access panel & pullout the mattress tray.
- ❖ Check the mattress tray should be locked and should not be come out.

2. Front Access panel Operation



Picture 26

- Rotate the locks and open the access panel.
- Pivot the access panel to the full open position.
- Close the access panel and check the locks are properly secured to avoid accidental opening of the panel.

3. Elbow port, Latches and Gaskets



Picture 27

- Press the pawl lock of each access door.
- The access door of the elbow port should swing open.
- Close the door and check for proper latching and quietness.
- Check the access door gaskets are placed properly on the inner and outer walls.

4. Side Access panel Operation



Picture 28

- Rotate the locks and open the access panel.
- Pivot the access panel to the full open position.
- Close the access panel and check the locks are properly secured to avoid accidental opening of the panel.

5. Iris Entry Ports:



Picture 29

- Rotate the outer ring of the Iris port(s), the Iris should open and close as the rotation is continued through 360°.

6. Air intake Micro filter

- A dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide build-up. Check filter on a routine basis and change at least every 3 Months.



Picture 30

- Pullout the air intake filters cover, inspect the micro filter; if visibly dirty, and replace it.



Warning

- A dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide built-up. Check the filter once in 15 days and change it at least every 3 months or when it is visibly dirty. Failure to do so could result in infant injury.

7. Oxygen Cylinder Connection



Picture 31

- Place and fix the regulator to the oxygen cylinder and ensure the knob is tightened.
- Connect the Oxygen hose to the tubing port. Supply the required oxygen into the oxygen input connector then monitor with calibrated oxygen analyzer level within the hood to verify that they reach the predicted level as indicated on the left side of the Infant Transport Incubator.

8. Collapsible operation



Picture 32

- Pull down and up the Infant Transport Incubator with trolley for the collapsible operation.
- Ensure it should be easily to pull down and pull up position.

2.11.3 Accessories Checks

Perform these checks if they are applicable.



Warning

- Limit the load of accessories to 5 Kgs per side on the Infant Transport Incubator to ensure stability. Accessories should not be mounted more than 56 inches (142 cm) above the floor.
- Due to the increased height of units with height adjustment, a tipping hazard may exist. Limit the total accessory load to 5 Kgs.



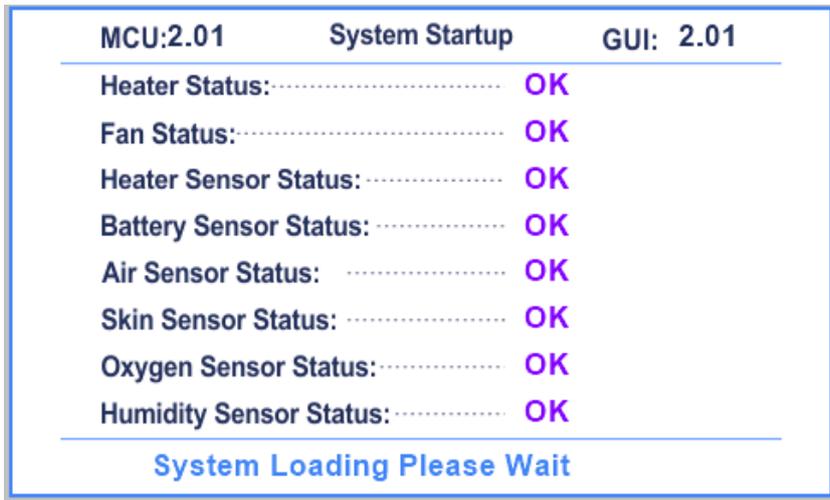
Caution

- Check that all accessories are mounted securely and that the load limits are not exceeded. Check that all gas accessories are installed and operating properly. Where applicable, perform the checkout procedures detailed in the Operation and Maintenance Manuals for the accessories.

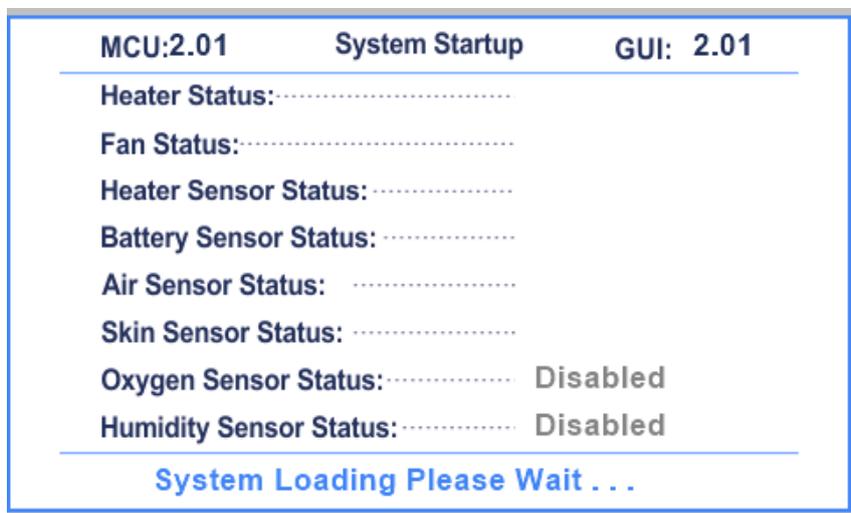
2.12 Controller Checkout Procedures

2.12.1 System Startup Operation

- When the Infant Transport Incubator is switched on, the device initiates a system startup process. The status of all critical component is checked before proceeding to normal operation.
- The status of each critical component is displayed with an indicator, such as "OK" to signify normal operation. Once all status is verified, the system will transition to the Control Panel Display. If any issue is detected, the status will show a "NOT OK" message to alert the user.



- After the system startup is complete, it will automatically transition to the Control Panel Display, where operations are monitored.



When the oxygen sensor status and humidity sensor status are in a disabled state, the control panel shows them as disabled.

Note: If the oxygen sensor or humidity sensor is disabled or skin sensor fails, the system will still transition to the control panel.

2.12.2 Air Control Mode Operation

- With all Access openings closed, allow the Infant Transport Incubator to warm up to the air set temperature of 36°C. It should take less than 45 minutes depends upon the Environment Temperature. When the air temperature display has stabilized, the digital display should remain within 0.5°C of the set temperature.
- The alarm will not generate at the initial power ON.

Note: Check the Air Temperature Display Window Shows 25°C when connect the calibrated test probe.

2.12.3 High/Low Air Temperature indication

- Open the Access panel. In approximately 5 minutes the alarm indicator should activate, the low air temperature visual indication should enable. Close the Access panel.

- Set the air temperature at 35°C, when the set temperature reached change the set value from 35°C to 36°C to raise the temperature 1°C greater than the set temperature, the high air temperature audio and visual alarm should indicate.

2.12.4 Skin Control Mode Operation

- With all Access openings closed, Place the skin probe 4 inches above the mattress center. Allow the Infant Transport Incubator to warm up to the Skin set temperature of 35°C. It should take less than 45 minutes depends upon the Environment Temperature. When the Skin temperature display has stabilized, the digital display should remain within 0.5°C of the set temperature.
- The alarm will not generate for at the initial power ON.

Note: Check the Skin Temperature Display Window Shows 25°C when connect the calibrated test probe.

2.12.5 High/Low Skin Temperature indication

- Set the Skin set temperature to 35°C. When the temperature Stabilizes, open the access panel. In approximately 5 minutes, the low Skin temperature visual and audio indication should Sound.
- Rub the skin temperature probe with hand to raise the temperature 1°C greater than the set temperature, the high Skin temperature audio and visual alarm indication should indicate.

2.12.6 Maximum Air Temperature

- Select the skin temperature mode and set temperature is greater 37°C. Place the skin probe outside the Infant Transport Incubator. Allow the Infant Transport Incubator to heat. If the skin temperature low indication sounds, press the Timed Acknowledged key. The Infant Transport Incubator should not heat above 39.9°C as indicated by the air temperature display. When reaching the air temperature at 39°C, over temperature indication should display indication and the heater should be OFF.

for air temperature by changing the mode to air

2.12.7 Skin probe sensor Disconnect indication

- In the skin mode fault condition, when disconnecting the skin probe from the socket. The audio indication Sound activates and the display shows "Skin sensor disconnect" (Sensor Open) and the heater supply will be cutoff. Reconnect the skin probe, the Infant Transport Incubator should return to normal operation generating the heater output as per the set temperature.
- The audio indication Sound activates and the display shown as high priority red indication in the pilot lamp with alarm.

2.12.8 Air sensor fault Disconnect indication

- In the Air mode fault condition, when disconnecting the air probe from the connector in SMPS. The audio indication sound activates and the display shows "Air sensor fault" and the heater supply will be cut off. Reconnect the air probe, the Infant Transport Incubator should return to normal operation generating the heater output as per the set temperature
- The visual indication activates and the display shown as high priority red indication in the pilot lamp.

2.12.9 Memory Back up, power Fail/Power Interruption

- **Memory Back up:** Switch to the Skin Mode. Set the skin set temperature at 36.5°C. Switch OFF the equipment. Switch On the equipment again. The mode and the set value should remain the same.
- **Power Fail/Power interruption:** In the absence of the power source supply of the AC, DC, or battery the power fail alarm and indication occur.

2.12.10 Battery backup operation

Plug the external AC power supply to the main supply and allow to charge initially for 8 hours charge and remove the power cord, the Infant Transport Incubator should work from the battery power.

2.12.11 External Direct Power Supply



Picture 33

- Plug the external 12V battery provided in the ambulance to the external DC power input socket and switch on the Infant Transport Incubator.



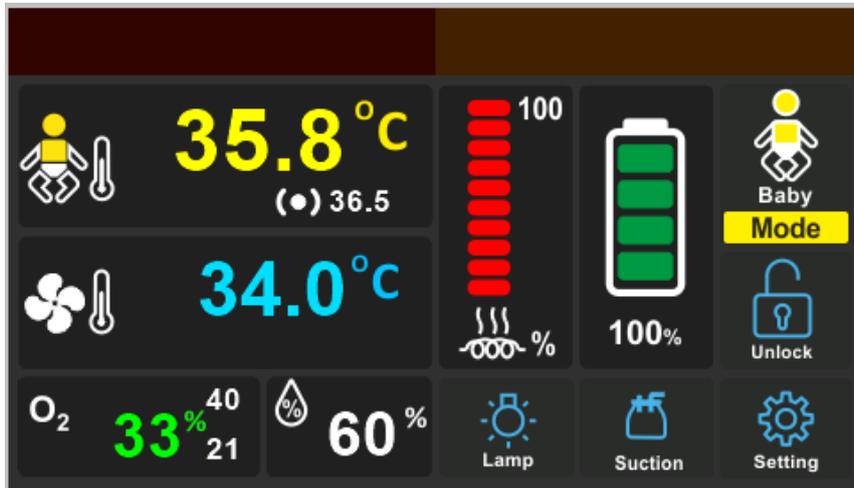
Warning

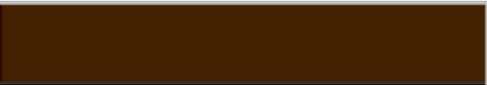
- Always connect the infant transport incubator with certified external 12V battery in ambulance.

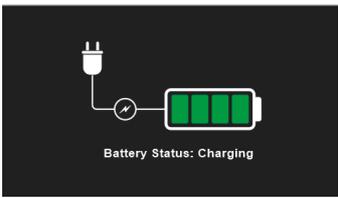
Section 3: Operation

- 3.1 TFT Touch Control Panel Display
- 3.2 Switches & Keys
- 3.3 General Control Panel Operation
- 3.4 Incubator Operation
- 3.5 Relative Humidity Monitor (Optional)
- 3.6 Oxygen Administration (Optional)
- 3.7 Settings
- 3.8 Audio & Visual Indication
- 3.9 Mattress Tray Operation
- 3.10 Front and Side Access Panel Operation
- 3.11 Humidifier Operation (Conventional)
- 3.12 Battery Charging Power Supply (SMPS)
- 3.13 Collapsible Trolley
- 3.14 Override
- 3.15 Shut down Procedure
- 3.16 Accessories

3.1 TFT Touch Control Panel Display



DISPLAY SYMBOLS	INDICATION	DESCRIPTION
	ALARM INDICATION	Indicates the high priority alarm.
	ALARM INDICATION	Indicates the medium/low priority alarm.
	SKIN TEMPERATURE & BABY SET TEMPERATURE	Baby's temperature and the baby set temperature is displayed.
	AIR TEMPERATURE & AIR SET TEMPERATURE	Air temperature and the air set temperature is displayed.

	<p>MODES SELECTION</p>	<p>Used to select modes such as baby mode, air mode and standby mode.</p>
	<p>HUMIDITY (Optional)</p>	<p>Relative humidity is displayed in percentage.</p>
	<p>OXYGEN (Optional)</p>	<p>Oxygen value is displayed in percentage.</p>
	<p>HEATER OUTPUT</p>	<p>The heater output is displayed as heater output percentage.</p>
	<p>BATTERY CHARGING STATUS</p>	<p>When the AC is connected, but the control panel switch is not on, it displays the battery charging status.</p>
	<p>BATTERY PERCENTAGE</p>	<p>The internal battery is displayed as internal battery percentage</p>
	<p>AC</p>	<p>When device runs through AC is displayed as AC and the battery is charged.</p>
	<p>EXTERNAL DC</p>	<p>When the AC is not connected and the DC is in enabled condition, it displays External DC.</p>

 <p>Suction</p>	<p>SUCTION (Optional)</p>	<p>The suction ON/OFF is controlled here.</p>
 <p>Lamp</p>	<p>OBSERVATION LAMP</p>	<p>Observation Lamp ON/OFF is controlled here.</p>
 <p>Unlock</p>	<p>LOCK/UNLOCK</p>	<p>Lock/unlock function is displayed.</p>
 <p>Setting</p>	<p>SETTINGS</p>	<p>It contains general, incubator, video, O₂ calibration, device info, advanced settings.</p>

3.2 Switches & Keys

	<p>Main switch</p>	<p>This switch is used to switch ON/OFF the device placed in the power supply unit.</p>
	<p>ON/OFF key</p>	<p>This key is used to switch ON/OFF the control panel</p>
	<p>Timed Acknowledged key</p>	<p>This key is used to Pause the audible indication for time duration. It Pauses indications except the power failure indication. The Timed Acknowledged indication key glows when in use.</p>

3.3 General Control Panel Operation

3.3.1 Observation Lamp

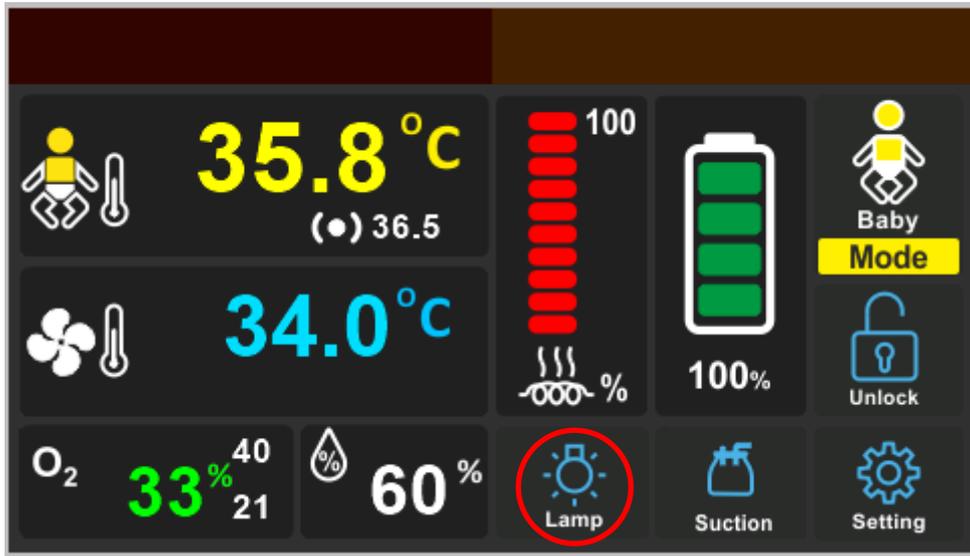
The lamp allows the physician to observe the growth of the baby and monitor baby's health conditions. The lamp light can be set for a duration of about 15, 30, 45 and 60 minutes as per the requirement of the physician



- Prolonged exposure to the light emitted by the observation lamp in this unit may harm the unprotected eyes of the infant. For safety, cover the infant's eyes.

To enable observation lamp, press the lamp icon on the control panel which is seen here:

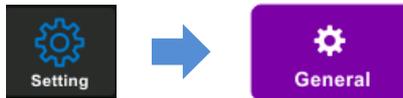
- Press the Lamp icon to enable the observation lamp function.
- To switch it OFF, press the same icon once.



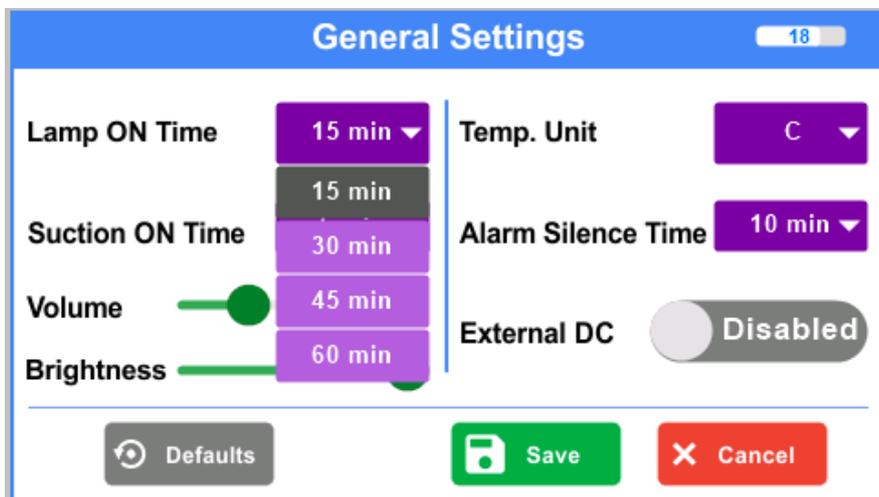
- To turn on the lamp, click the lamp icon. The icon will change to blue, indicating that the lamp is ON.



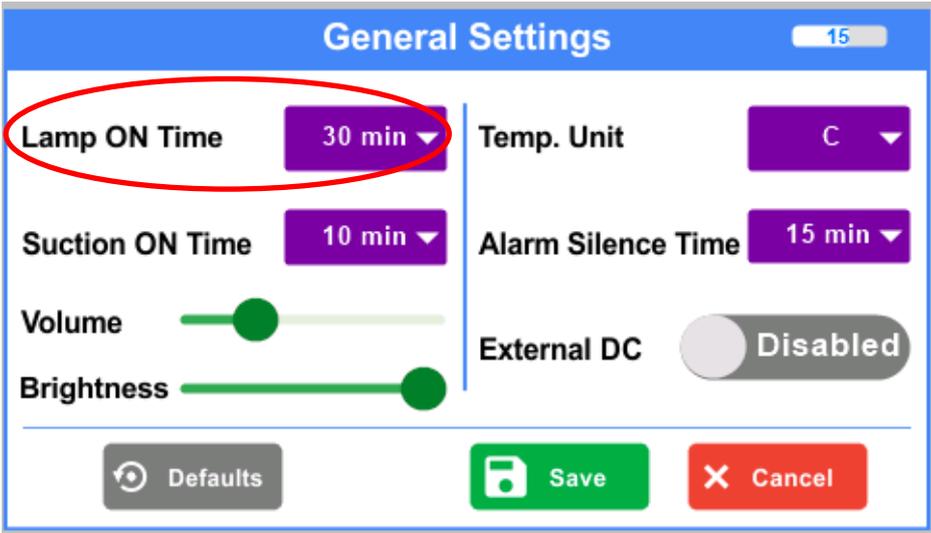
- To Set the Lamp time, click the Setting icon, then navigate to General in the Setting window.



- General setting displays, required time duration of the observation lamp can be set, by selecting the option Settings



Defaults: Set time of the observation lamp can be changed to default time of 30 min.



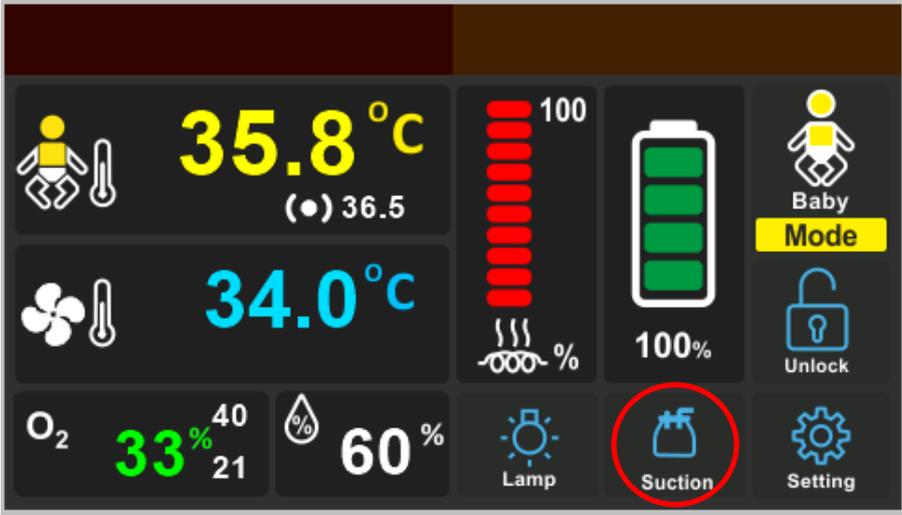
3.3.2 Suction (Optional)

The Suction function allows the physician to use the operation during requirement of the baby's health conditions. The function can be turned ON/OFF. When switched ON, the suction time can be selected between 5 or 10 or 15 or 20 minutes.

Suction sucks atmospheric air to generate vacuum with the help of the motor present in the suction unit and creates suction to remove secretions from the baby respiratory tract.

To enable suction, press the suction icon on the control panel which is seen here:

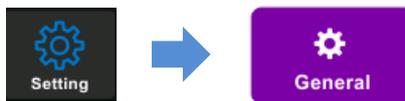
- Press the Suction icon to enable the Suction function.
- To switch it OFF, press the same icon once.



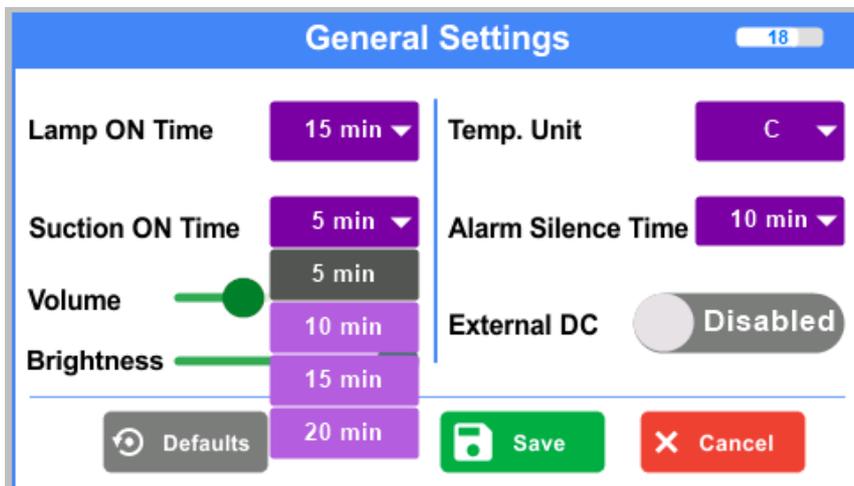
- To turn on the Suction, click the Suction icon. The icon will change to Yellow, indicating that the Suction is ON.



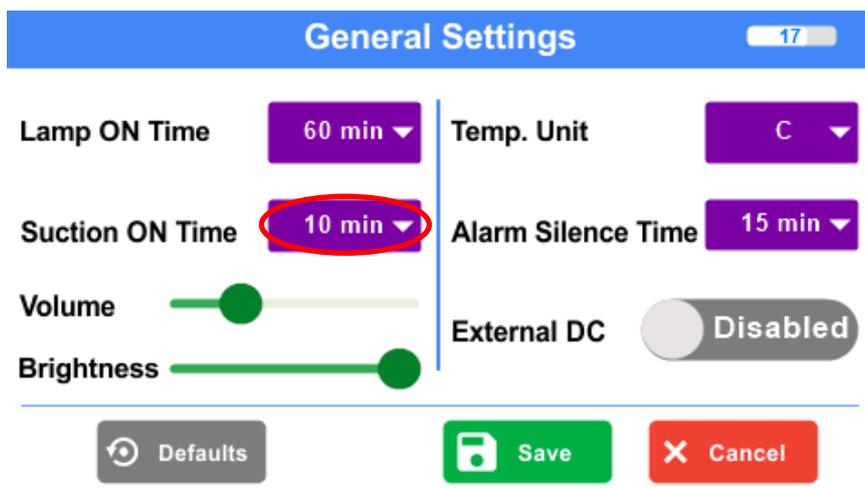
- To Set the Suction ON Time, click the Setting icon, then navigate to General in the Setting window.



- The required time duration of the suction can be set, by selecting the option Settings.



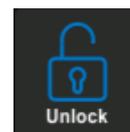
Defaults: Set time of the suction can be changed to default time of 10 min.



3.3.3 Lock function

The lock function in the control panel locks the control panel display from making any changes other than the user or physician. Both lock and unlock functions can be done by pressing the lock/unlock icon.

- When the control panel is locked, the below icon is displayed.
- Press the icon in the control panel to unlock.
- When the control panel is unlocked, the below icon is displayed.
- Press the icon in the control panel to lock.

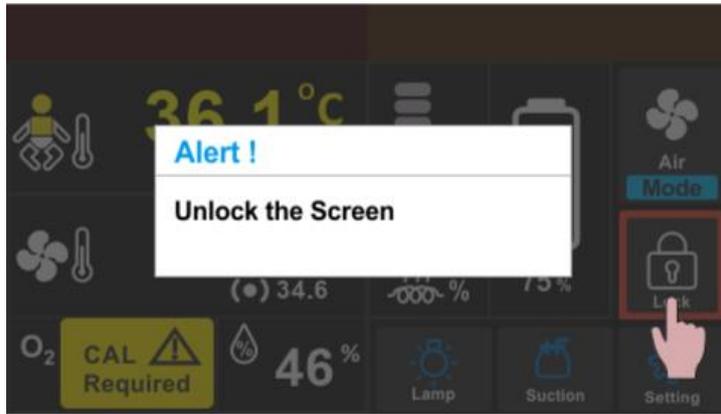


Note: Only the following functions can be accessible when the Lock has been enabled.

1. Observation Lamp ON/ OFF
2. Suction ON/ OFF

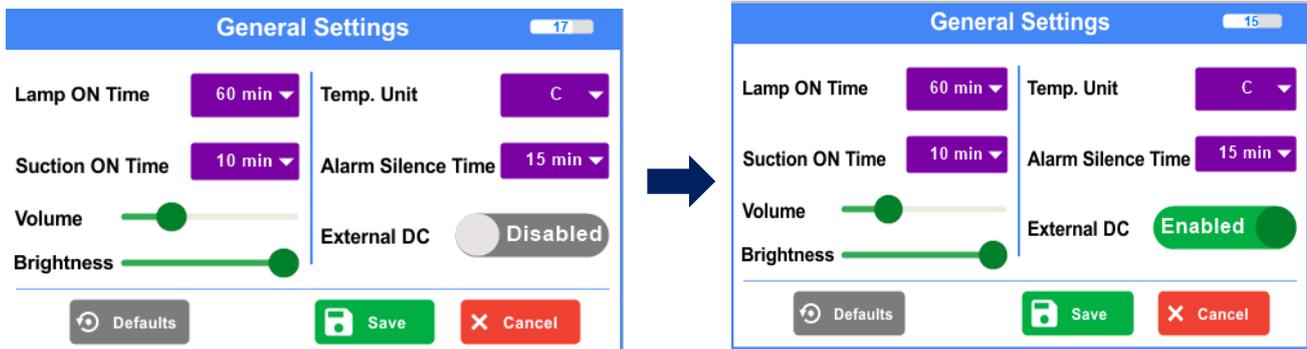
All the other icons are inaccessible when lock function is enabled.

Note: A dialog box with alert message as “Unlock the screen” appears when control panel is accessed with lock function enabled.



3.3.4 External DC

External DC power is used to ensure a reliable and continuous power supply during transport.



To enable the External DC, slide the Disable option; this will activate the external DC power.

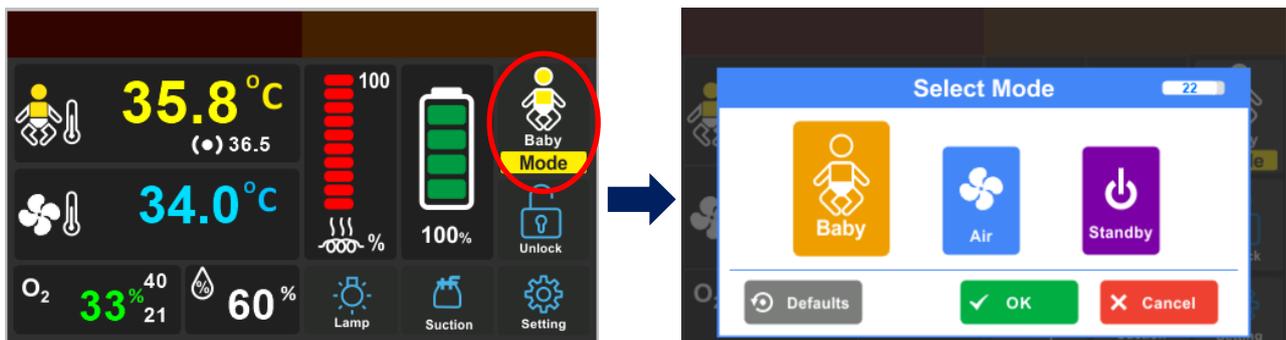
3.4 Incubator Operation

3.4.1 Mode selection

Infant Transport Incubator mode can be selected through the following process:

Select MODE option in the control panel (red circled)

Select the desired mode and then press OK



Defaults: Set temperature of the Baby and/or Air modes can be changed to default temperature.

3.4.2 Baby Mode (Skin Mode)

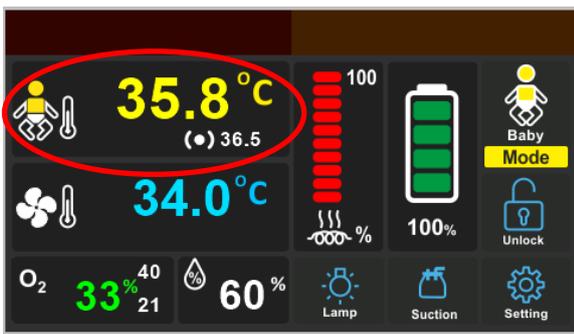
Note: The skin temperature sensor must be properly attached before starting Baby mode operation.

- The skin control temperature (Set required Temperature) enables the user to select the required settings when the Infant Transport Incubator is used in the Baby mode for the first time. The control panel enables the user to make this setting with an operator prompt tone and the changing of the control temperature display.
- The Skin control temperature is adjusted by pressing the increase (+) and decrease (-) touch switches. The control temperature can be adjusted from 30° to 39°C
- In the Baby mode, the temperature sensed by the skin temperature sensor is used by the control system to modulate the radiant heat and maintain the patient's temperature at the selected control temperature.

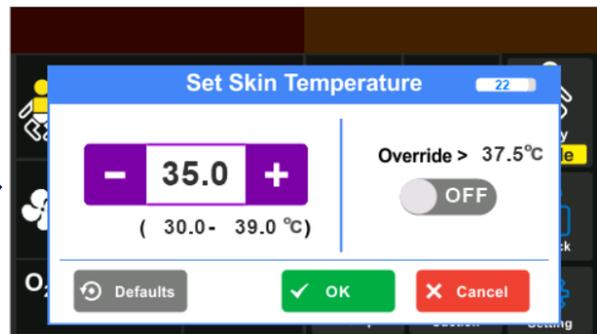
Note: The Infant Transport Incubator cannot differentiate between an increase in core temperature with cold skin (fever), and low core and Skin Temperature (hypo-thermia). Patient temperature should be verified with an ancillary thermometer.

To set the required temperature, follow the steps given below:

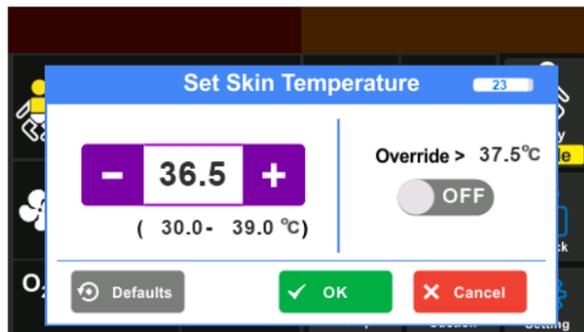
Select Skin Temperature in the control panel
(red circled)



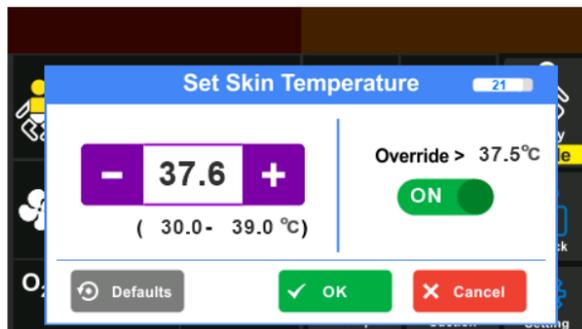
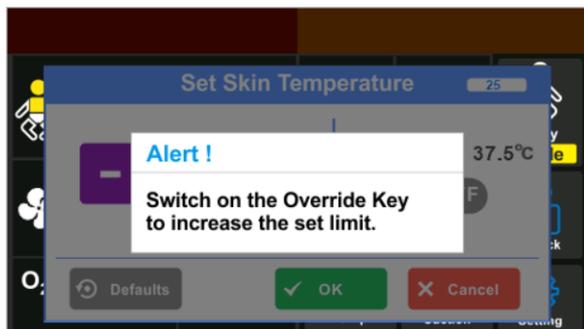
Select the desired temperature by increasing or decreasing key and then press OK



Defaults: Set Skin temperature of the baby mode can be changed to default Skin temperature with 36.5°C.



- **Override Function:** If override function is enabled, in ON condition the control temperature can be adjusted from 37.6° to 39°C. And when disabled, in OFF condition the control temperature can be adjusted only from 30° to 37.5°C and cannot be exceeded from 37.6° to 39°C.



Warning

- Periodically monitor the infant temperature sensor it may remove from the skin due to poor affixing, poor adhesive of the tape. It may cause over heating of the baby.
- In the baby mode, verify that the patient temperature sensor is securely attached to the patient at least every half an hour. A dislodged sensor does not always trigger an indication. If the sensor becomes dislodged, the Infant Transport Incubator can result in over temperature or reduced temperature of the infant.

Note: A patient placed in any Infant Transport Incubator will normally develop temperature gradients with hotter and cooler areas. This is due to radiant heat being applied above the infant, the unequal skin cooling effect from evaporative water loss, unequal heat generation within the patient, and the environmental variables of room temperature, room air movement, incidental sunlight, etc.



Warning

- The use of LED based phototherapy equipment may raise the patient's temperature.

3.4.2.1 Skin Temperature Probe Attachment



Warning

- Use only the Reusable nice Neötech skin temperature sensor to monitor the baby's temperature. Use of other manufacturer's sensors may affect the accuracy of Infant Transport Incubator operation and the electrical safety of the patient.
- The skin temperature sensor should be located on the patient's skin in an area which is directly in the path of the radiant heat. It should not be attached to an area which is shielded from the radiant heat or between the patient and the mattress. Large temperature gradients and very long skin response times will result from improper sensor placement.
- Rectal temperatures must never be used to skin control patient's temperature.

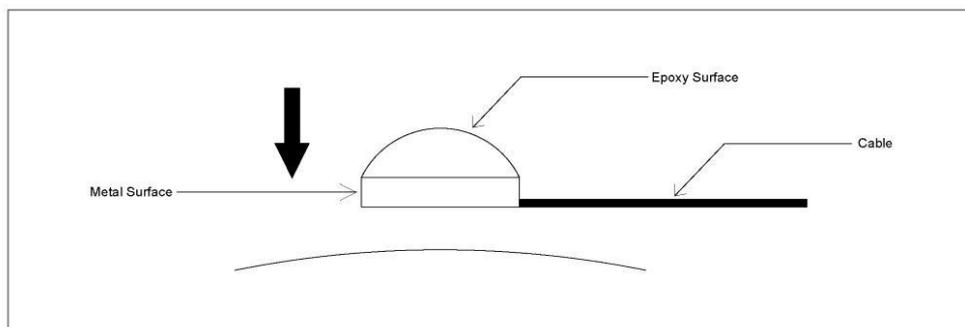


Figure 2

- The nice Neötech Patient sensor lead is made from low mass wire that helps prevent sensor detachment while reducing pulling on the neonate's skin.
- Place the metal side of the skin temperature sensor on the skin over the liver area of the infant's abdomen. Remove the paper protecting the hypoallergenic adhesive on the Heat Reflective Patch. Secure the skin temperature sensor to the patient's skin with the adhesive side of the patch.

Note: The sensor jack is attached at a specific torque value. Loosening or tightening the jack may break the electrical connector.

- ❖ If the patient is prone, place the skin temperature sensor on the back, where it will not be against the mattress. If the sensor is between the patient and the mattress, it will produce false readings.
- ❖ Connect the skin temperature sensor to the Infant Transport Incubator by plugging the sensor connector into the left side of the Connector as viewed from the front.



Warning

- Intimate contact between the skin temperature sensor tip and the patient's skin must be maintained for accurate Skin Temperature measurement. Under heating or overheating may result from poor contact between the skin temperature sensor and the patient. Verify that the skin temperature sensor is securely attached to the patient at least once every half an hour.
- Periodically monitor the infant Temperature Sensor it may remove from the Skin due to poor affixing, poor adhesive of the tape. It may cause over heating of the baby.



Caution

- Always remove the sensor from the patient by grasping and removing the heat reflective patch first, and then remove the sensor from the patient or the patch. Always remove the sensor from the Infant Transport Incubator by grasping the plug at the panel. Placing excessive strain on the skin temperature sensor lead can damage the sensor.

Note: Avoid placing excessive strain on the skin temperature sensor lead. Always remove the sensor by grasping the plug at the panel. Do not pull on the sensor lead.

3.4.3 Air mode

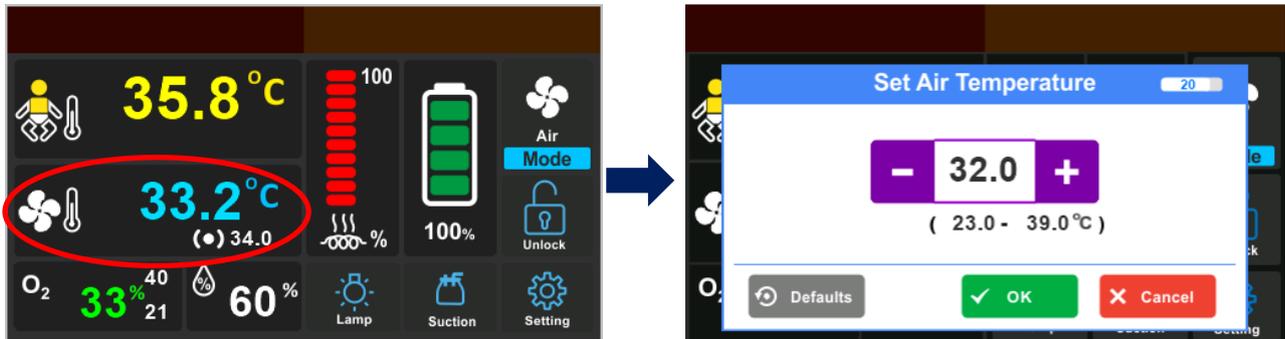
Note: The Air temperature sensor must be properly attached near fan construction unit of the Infant Transport Incubator before starting air mode operation.

- The air control temperature (Set required Temperature) enables the user to select the required settings when the Infant Transport Incubator is used in the Air mode for the first time. The control panel enables the user to make this setting with an operator prompt tone and the changing of the control temperature display.

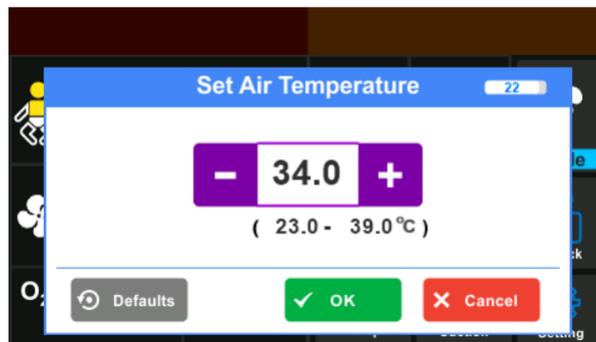
To set the required air temperature, follow the steps given below:

Select Air temperature in the control panel
(red circled)

Select the desired air temperature by increasing or decreasing key and then press OK



Defaults: Set Air temperature of the Air mode can be changed to default Air temperature with 34.0°C.



Setting of Air Control Temperature

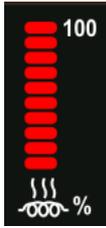
- ❖ The air control temperature is adjusted by pressing the increase (+) and Decrease (-) switches. The control temperature can be adjusted from 23°C to 39°C. In the air mode, the temperature sensed by the air temperature sensor is used by the control system to modulate the radiant heat and maintain the environment temperature at the selected control temperature.

Note: The Infant Transport Incubator cannot differentiate between an increase in core temperature with cold skin (fever), and low core and skin temperature (hypothermia). Patient temperature should be verified with an ancillary thermometer.



- In the air mode, verify that the air temperature probe is securely attached near fan construction unit of the Infant Transport Incubator before starting air mode operation. A dislodged sensor does not always trigger an indication. If the sensor becomes dislodged, the Infant Transport Incubator can over or under heat the infant.
- If disconnection of air probe, should contact nice Neötech personnel.

Note: Heater output power bar comes in 3 colours which is shown below:

Heater Output power bar color			
Colours	Green	Amber	Red
Range	0 – 30%	40 – 70%	80 – 100%

3.4.4 Standby mode

This key activates Standby Mode. In this mode, the heater output is 100% for 10 minutes and after 10 minutes heater output will be reduced to 30%.

3.5 Relative Humidity Monitor (Optional)

- ❖ Prewarm the incubator in Air mode to the temperature prescribed by the attending physician or according to Nursery Standing Orders.
- ❖ The humidity module is used to check the humid present inside the canopy hood.



Warning

- Higher relative humidity will, at any given time, decrease an infant's evaporative water loss, and may cause an increase in infant temperature. This effect is greatest in very low birth-weight, premature infants. The attending physician should prescribe Temperature Control mode, temperature setting, and humidity output level setting. Routinely monitor the infant's rectal and/or axillary temperature according to the attending physician's orders or Nursery Standing Orders. Failure to do so could result in personal injury.

Note: At humidity levels greater than 70 RH%, condensation may form on the inside walls of the hood. By continuous checking of the humidity output percentage, the sponge can be made wet by pouring the distilled water

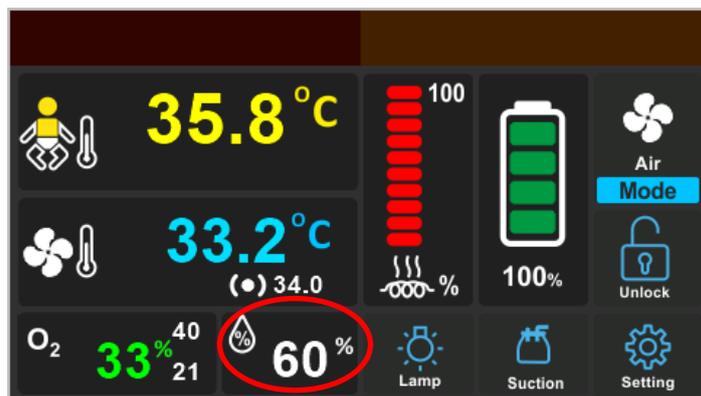


Caution

- To prolong the useful life of the humidity module, use only distilled water. Sterile water is not an acceptable substitute for distilled water. Equipment damage could occur.

The humidity maintained inside the hood is checked and displayed in the control panel display.

The relative humidity output display in the control panel (red circled)



3.6 Oxygen Administration (Optional)

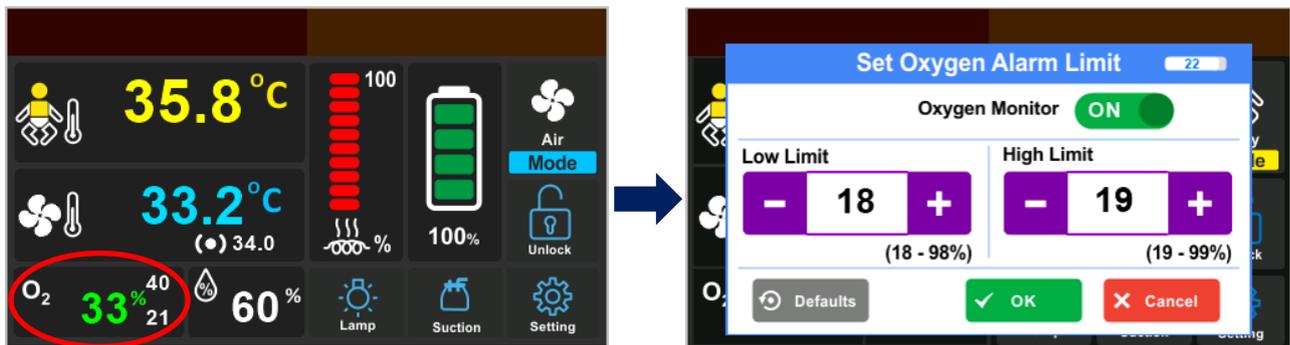
In oxygen administration, the oxygen sensors present in the Oxygen humidity sensor control module is used to check the concentration level of oxygen present inside the hood and to indicate the oxygen limit when oxygen concentration rises above or falls below the set limits (Low limit (18-98%) and high limit (19-99%)). The Audio and Visual Indication limit default is $\pm 3\%$ from the current set point. If the oxygen concentration rises above or falls below the $\pm 3\%$ limit, an audible and visual Audio and Visual Indication occurs.

Note: Oxygen percentage displayed only when enabling the Oxygen Monitor from OFF to ON.

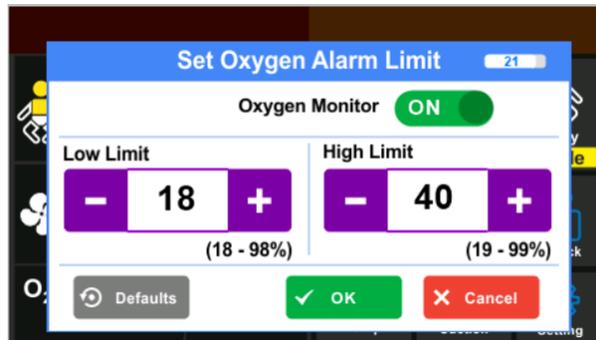
To set the oxygen percentage, follow the steps given below:

Select the oxygen percentage in the control panel
(red circled)

Select and set the required level of oxygen alarm
limit percentage by increasing (+) or decreasing (-)
key and then press OK



Defaults: Set Oxygen Alarm Limit can be changed to default limit.



Warning

- Oxygen concentrations higher than 40% can increase the risk of retrolental fibroplasia (retinopathy of prematurity). It is probable that even concentrations of 40% or less oxygen (formerly considered safe) could be dangerous to some infants. Therefore, arterial blood gas measurements are extremely important for regulation of the concentration of inspired oxygen when an oxygen administration is considered necessary. (See current edition of "Standards and Recommendations for Hospital Care of Newborn Infants" prepared by the Committee of Fetus and Newborn of the Academy of Pediatrics.)

Note: Discontinue therapy while replacing cylinders.

Oxygen addition: If oxygen is added, the Safety instructions described under "Precautionary measures when using oxygen" must be strictly observed.



- Oxygen addition only under medical direction.
- Oxygen can be administered from auxiliary oxygen cylinder through the flow meter.
- If Oxygen is added to the entire Infant Transport Incubator via the unit connector, the following concentrations can be obtained with an Oxygen Flow meter:
 - 2 L/min 25%
 - 4 L/min 30%
 - 6 L/min 40%
 - 8 L/min 50% (figures should be considered Nominal Values)
- The oxygen Concentration must be monitored with a calibrated oxygen measuring unit the head of the patient.



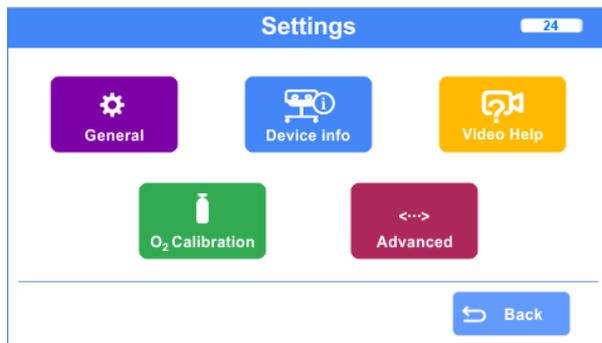
- Make sure that the oxygen supply to the incubator is turned off and that the incubator is disconnected from the oxygen supply when performing cleaning procedures. A fire and explosion hazard when cleaning in an oxygen administration.
- The use of oxygen increases the danger of fire and the auxiliary equipment producing spark shall not be placed in the equipment.
- Even a small quantity of flammable agents such as ether and alcohol, left in the incubator it can cause fire in connection with oxygen.
- The administration of oxygen may increase the noise level for the baby within the incubator.
- Oxygen flow rates cannot be used as an accurate indication of oxygen concentration in an incubator. Continuously monitor the oxygen concentrations with a calibrated oxygen analyzer. Failure to do so could result in Personal injury or equipment damage.
- If the patient's arterial oxygen levels cannot be maintained when the oxygen control settings is set to maximum, the attending physician should prescribe alternate means of oxygenation. Failure to do so could result in personal injury or equipment damage.

3.7 Settings

The settings instructions of nice 3000 are given here:

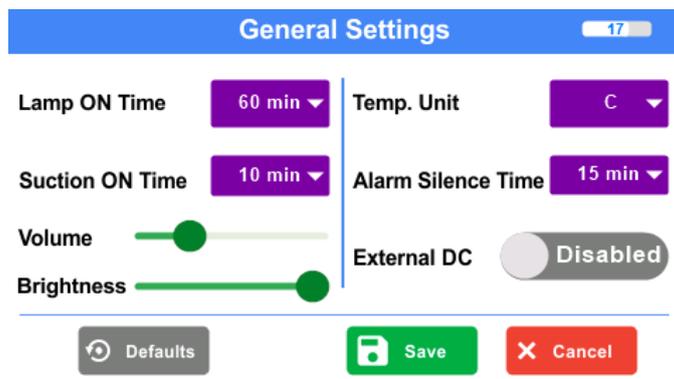
Factory Default: The factory default key allows to default the set values.

Select SETTINGS



3.7.1 General settings

The general settings contain the following:



Lamp ON Time: The observation lamp timer can be selected by the user to switch ON the lamp for 15 or 30 or 45 or 60 minutes.

Temperature Unit: Centigrade (°C) or Fahrenheit (°F)

Suction ON Time: The suction time can be selected between 5 or 10 or 15 or 20 minutes when switched ON.

Alarm Silence Time: The alarm pause can be selected by the user for 10 or 15 minutes.

Volume: Adjust the volume level using sliding action.

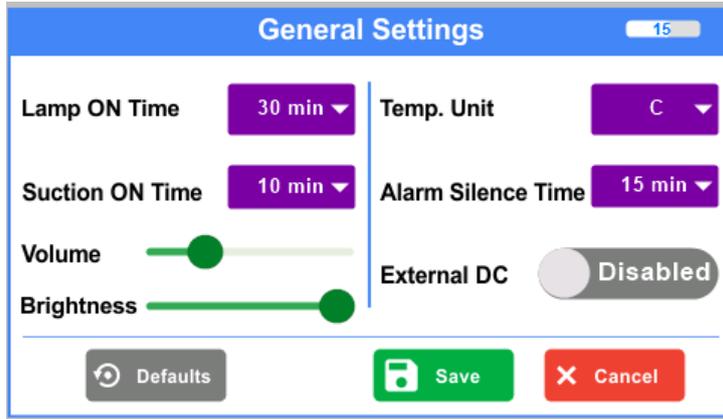
Brightness: Adjust the Brightness level using sliding action.

External DC: The External DC can be enabled by sliding the External DC option.

Save: The set values can be saved using the Save option.

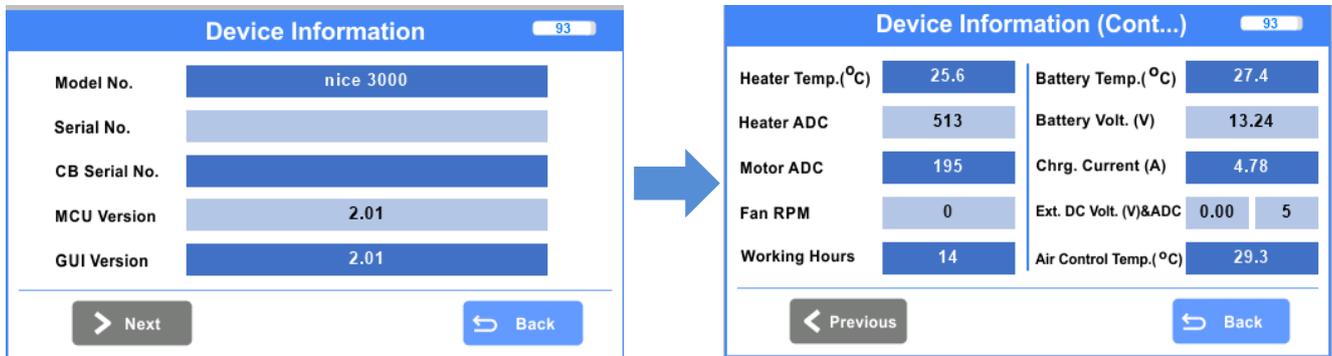
Cancel: The General settings display is closed using the Cancel option.

Defaults: The all set values of time and temperature unit can be changed to default values as shown below.



3.7.2 Device Info Settings

The Device Info Settings contain the following:



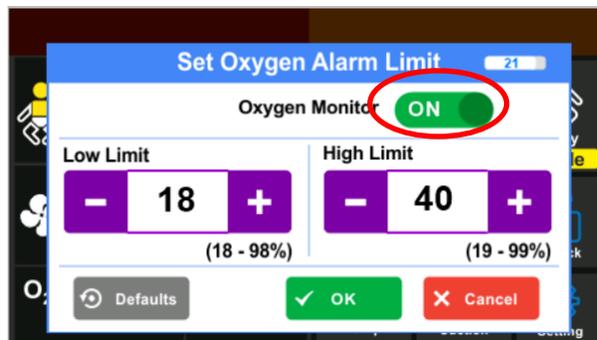
The device information screen displays essential details, including the Model No, Serial No, CB Serial No, MCU version, GUI version, Heater Temperature, Heater ADC, Motor ADC, Fan RPM, Working Hours, Battery Temperature, Battery Voltage, Charging Current, External DC Voltage & ADC, and Air Control Temperature.

Note: This information is intended for service personnel to diagnose and resolve any equipment issues.

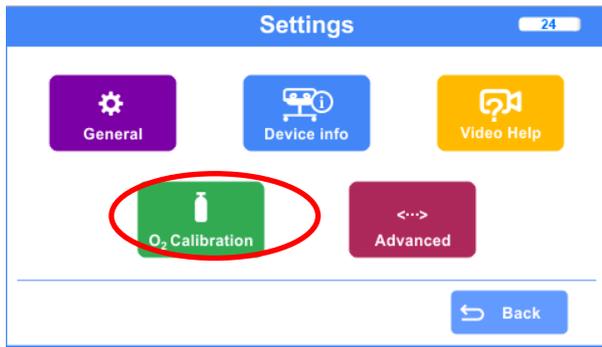
3.7.3 Oxygen Calibration

Oxygen sensor module should be calibrated before each and every use to maintain accuracy for continuous use.

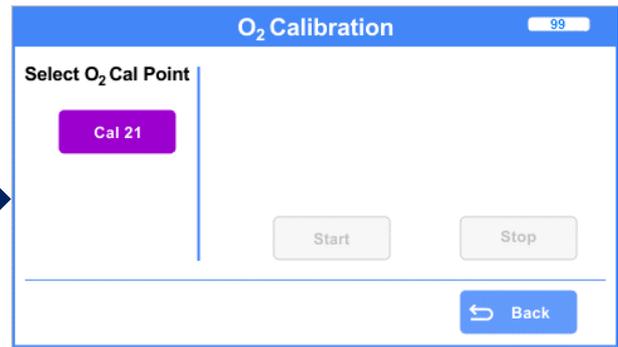
Note: Oxygen can be calibrated only when enabling the Oxygen Monitor from OFF to ON.



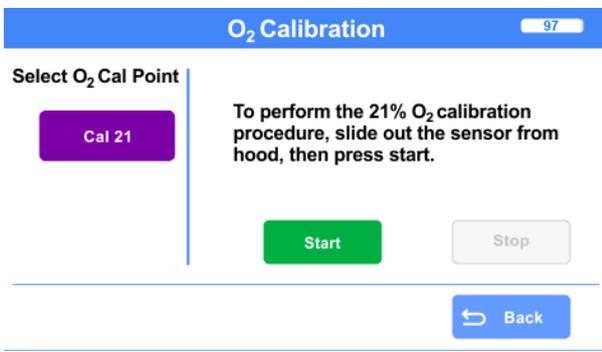
Select settings and Go to the Oxygen Calibration settings.



Choose CAL 21% to perform calibration.



When CAL 21% is pressed, the procedure given in the dialog box is performed as such by the user.

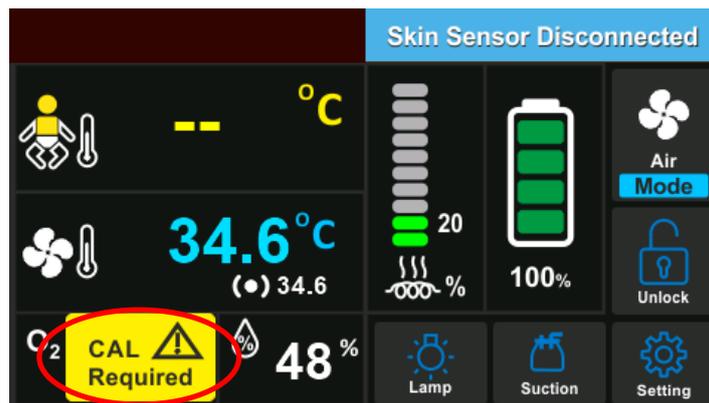


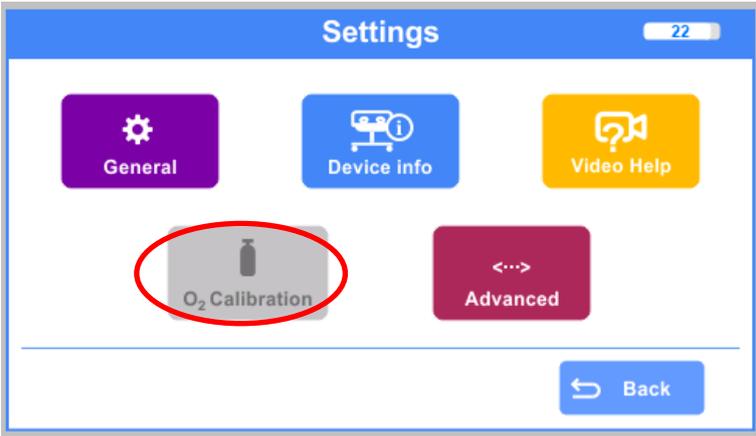
After Pressing the Start option, Please wait is displayed on the screen for few second , then Calibration Success is displayed



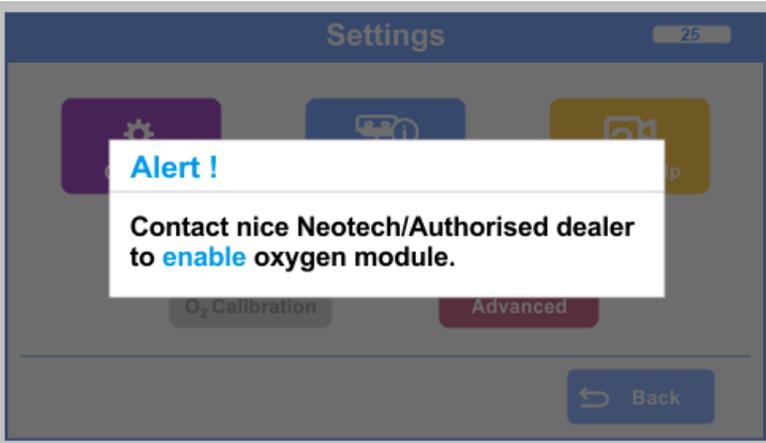
Note: "CAL Required" indication will displayed with the caution symbol whenever connecting of new oxygen sensor probe reconnecting of oxygen sensor probe.

"CAL Required" will displayed (red circle)





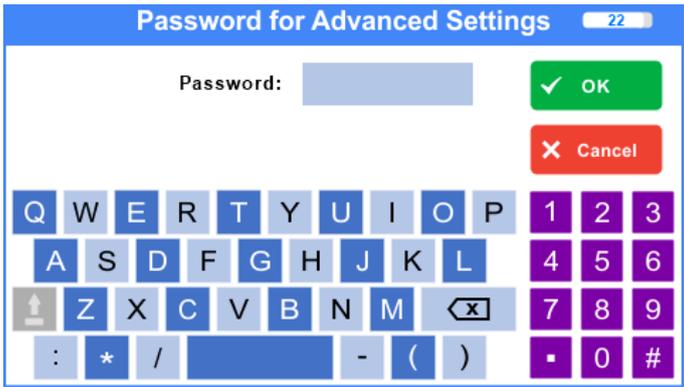
Note: When oxygen calibration is disabled, it is displayed in gray on the settings page.



Note: A dialog box with alert message as “Contact nice Neotech/Authorised dealer to enable oxygen module” appears when control panel is accessed with oxygen calibration disabled.

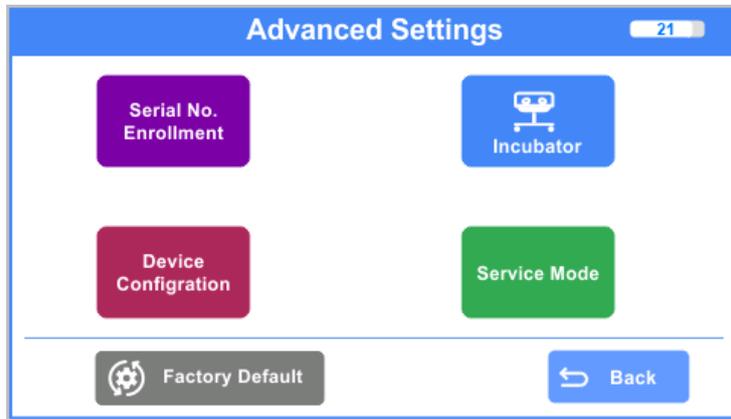
3.7.4 Advanced Settings

To access the Advanced Settings, a password is required.

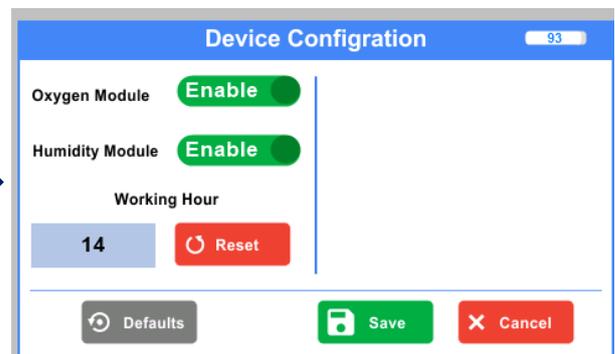
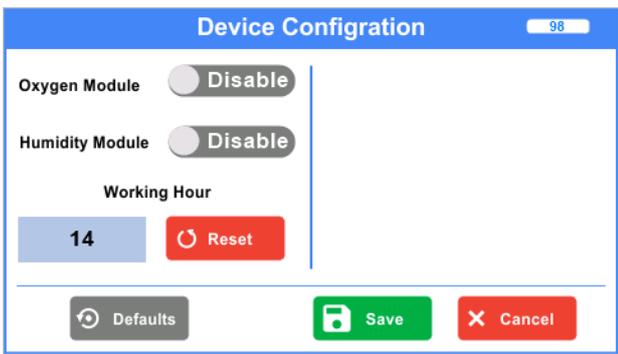


Note: This password is intended for use only by nice Neotech/ Authorised dealers.

The Advance settings of nice 3000 are given here:



3.7.4.1 Device Configuration



To enable the oxygen and humidity modules, Select Device Configuration, where the oxygen and humidity modules are shown in the disabled state. Slide the toggle from Disable to Enable to activate the oxygen and humidity modules. The working hours of the device can also be reset in the device configuration option.

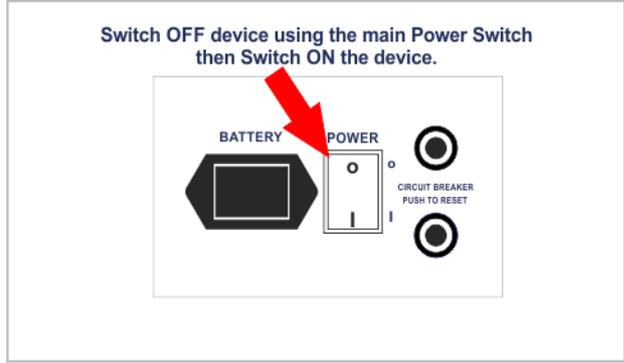
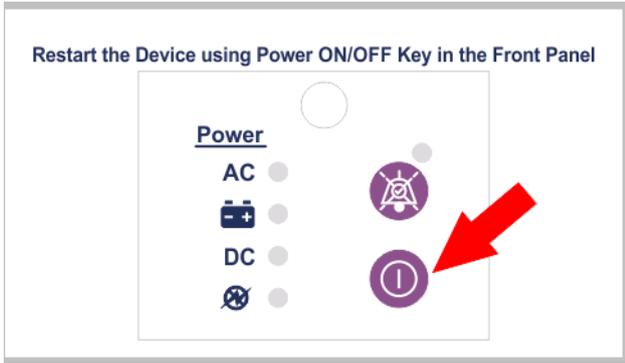
Select the Save option, click yes to complete the activation of the oxygen and humidity modules.

After selecting yes, "Please Wait" message will appear.



Restart the Device using Power ON/OFF Key in the Front Panel to activate.

Switch OFF the device using the main Power Switch then Switch ON the device.



After completing this procedure, the oxygen and humidity modules will be enabled, and the working hours will be reset.

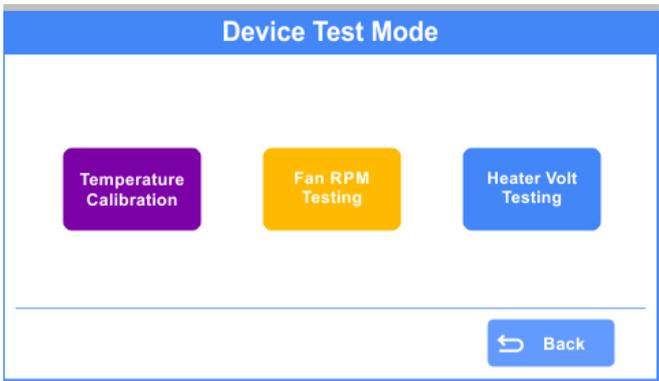
Note: When the internal battery is connected, the device needs to be restarted using the Power ON/OFF key on the front panel to activate. However, when both the internal battery and AC power are connected, the device needs to be switched OFF using the main power switch, then switched ON again.



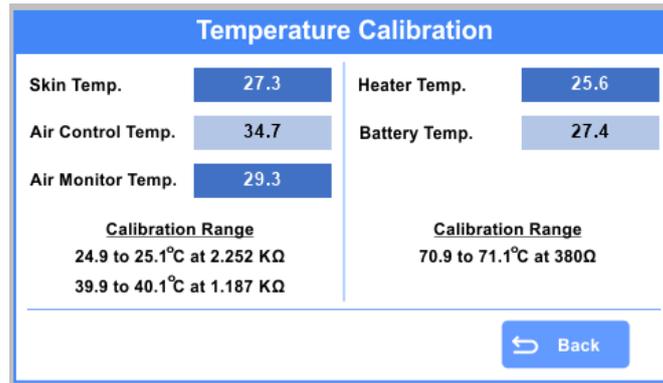
Note: When the oxygen and humidity modules are not enabled, it is indicated as shown on the control panel display.

3.7.4.2 Service Mode

Select Service Mode to access the Device Test Mode, which displays options for Temperature Calibration, Fan RPM Testing, and Heater Voltage Testing. This mode is intended primarily for service purposes.

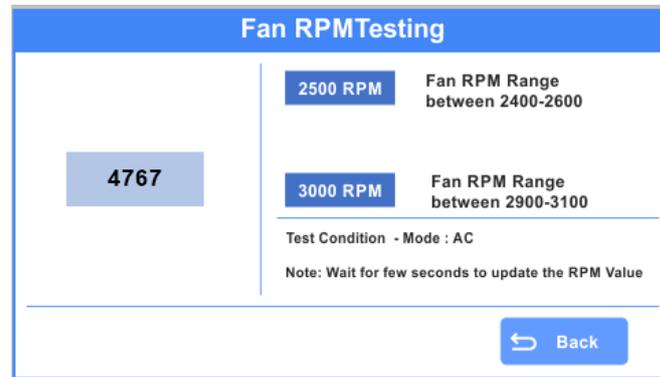


Temperature Calibration



The Temperature Calibration screen displays values for Skin Temperature, Air Control Temperature, Air Monitor Temperature, Heater Temperature, and Battery Temperature, along with their corresponding calibration ranges.

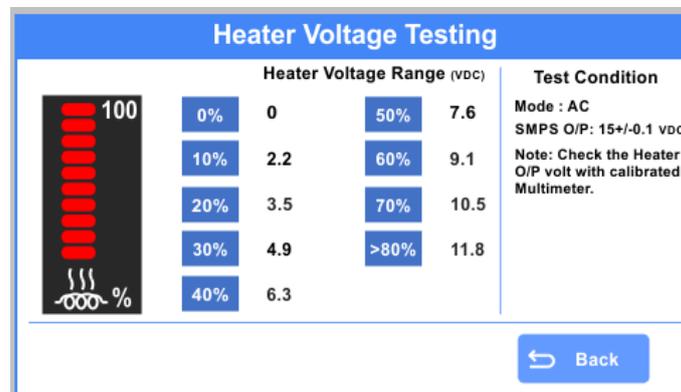
Fan RPM Testing



The Fan RPM Testing screen shows the RPM range, and the test condition mode for this is AC.

Note: Wait for few seconds to update the RPM value.

Heater Volt Testing



The Heater Voltage Testing screen displays the heater voltage range, and the test condition mode to use is AC.

Note: Check the heater output voltage using a calibrated multimeter.

3.8 Audio & Visual Indication

3.8.1 Alarm priorities

An audio and visual indication occurs when there is an alarm or an emergency to attend to the patient. The alarm indication occurs when it exceeds the set limit with colour codes.

According to the levels of priority, color coded visual lamp indication along with alarm priority flashes indication rises. Color codes for visual alarm indication and alarm priorities are explained in 3.8.2

Orchid unit distinguishes the following Audio & Visual Indication:

Alarm Priority	Alarm message	Alarm Description
High Priority	Skin over temp.	Display when Baby's skin temperature exceeds 39°C.
	Air over temp.	Display when Air temperature exceeds 39°C.
	Skin Sensor Disconnect	Display when the skin probe sensor gets disconnected or fails to sense the skin temperature from the baby in Baby mode.
	Air Sensor fault	Display when the Air probe sensor gets disconnected or fails to sense the temperature inside the hood.
	Heater Fault	Display when the heater is defected or disconnected from the equipment in any mode of operation.
	Heater sensor Fault	Display when the heat sensor gets disconnected or fails to sense or control the heat.
	Fan Fault	Display when the fan fails to rotate.
	Air Flow Fail	Display when the air flow temperature reaches to >78°C.
	Skin Sensor Fault	Display when the skin sensor gets short or fails to sense in baby mode.
Medium Priority	Skin temp. high	Activates when baby's skin temperature raises more than 1°C from the set required temperature in Baby mode.
	Skin temp. low	Activates when baby's skin temperature decreases less than 1°C from the set required temperature in Baby mode.
	Air temp. high	Activates when air temperature raises more than 1°C from the set required temperature in Air mode.
	Air temp. low	Activates when air temperature decreases less than 3°C from the set required temperature in Air mode.
	Oxygen Sensor Disconnected	Display when the Oxygen probe sensor gets disconnected or fails to sense the Oxygen present inside the hood.
	Oxygen High	Display when the oxygen present inside hood exceeds by 1% from the set oxygen alarm limit.
	Oxygen Low	Display when the oxygen present inside hood less than by 1% from the set oxygen alarm limit.
	Humidity sensor Disconnected	Display when the humidity sensor gets disconnected.
Low Priority	Skin Sensor Disconnect	Display when the skin probe sensor gets disconnected or fails to sense the skin temperature from the baby in Air and Standby mode.
	Fan Flow Low	Activates when the fan flow decreased to 1500RPM

	Skin Sensor Fault	Display when the skin sensor gets short or fails to sense in Air and Standby mode.
--	-------------------	--

NOTE: Above mentioned alarm conditions cause an audible and visual alarm without any delay.

NOTE: All the above audio alarms except power failure can be paused using the Audio pause key on the hood.

NOTE: If a second indication is triggered while the audible indication is Timed Acknowledged key, the audible indication will be reactivated.



- In the baby mode, verify that the patient temperature sensor is securely attached to the patient at least once every half an hour. A dislodged sensor may not trigger an indication. If the sensor becomes dislodged, the Infant Transport Incubator can over or under heat the infant.
- The skin temperature sensor should be located on the patient's skin in an area which is directly in the path of the radiant heat. It should not be attached to an area which is shielded from the radiant heat or between the patient and the mattress. Large temperature gradients and very long skin response times will result from improper sensor placement.

3.8.2 Visual alarm indicator

A visual alarm indicator is fixed on the Incubator hood to produce different audio and visual indications for medium and high priority alarms other than the control panel. It produces visual indications based on colors such as pink for self-test, green for normal condition, amber for medium priority alarms, red for high priority alarms and blue for low priority alarms. The color codes for visual indications are explained here:

Indication color	Description
	Self-test
	Normal operation
	High priority alarm
	Medium priority alarm
	Low priority alarm

3.9 Mattress Tray Operation



Picture 34

- ❖ The Mattress tray can slide through the side panel for procedures.
- ❖ The mattress has the restraining baby straps to secure the baby when transport.
- ❖ The mattress can be removed from the shell by pressing the lock towards down and pull the mattress tray out for cleaning the mattress tray and shell.



Warning

- Inspect all patient connected tubes or wires before and after moving or tilting the bed. Tilting or moving the Infant Transport Incubator bed up or down can pull on tubing or leads connected to the patient. This may disconnect tubes or leads, restrict gas or liquid flow, or move sensors out of position.

3.10 Front and Side Access Panel Operation



Picture 35



Picture 36

- ❖ Rotate the locks and open the access panel. Pivot the access panel to the full open position. After completion of the procedure close the access panel and lock it.

Important: Never place patient in cold Infant Transport Incubator. Reclose front flap (front door)

3.11 Humidifier operation (Conventional)



Picture 37

- ❖ Open the side access door of the hood
- ❖ Pull out the mattress tray from the lower unit.
- ❖ Pour the distilled water of 450ml over the sponge being placed at the sponge compartment to making it wet for humidification process.
- ❖ Place mattress tray above it and lock the hood door. When the fan is turned on the air inside the canopy will gain humidity from the wet sponge.



Warning

- nice 3000 have Conventional Humidity System and hence humidity of inside hood is not controlled by the equipment.

3.12 Battery Charging Power Supply (SMPS)



Picture 38

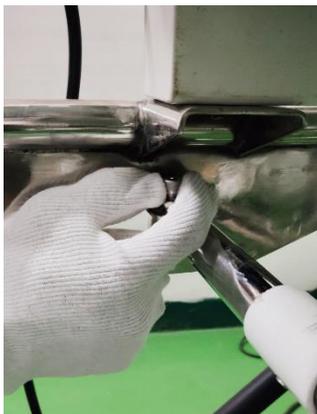
- ❖ The battery charger SMPS is placed in the power supply unit. To switch ON the battery charger SMPS, turn ON the AC supply and the main power switch.
- ❖ Three LEDs in the Control panel indicate the power status, if the equipment is working in Mains (AC), External DC supply, or Battery.
- ❖ The TFT display indicates the battery level in percentage, if the equipment is operating in battery.
- ❖ When the Infant Transport Incubator is again connected to the mains current the battery is charged automatically
- ❖ Over charging cut off is provided, when charging is completed.

3.13 Collapsible Trolley



Picture 39

- ❖ To transport inside the hospital, release the lock and un-collapse the trolley by lifting using handles on both sides.



Picture 40



Picture 41

- ❖ Lock the trolley by using screw to prevent from the sudden collapsible of the trolley.



- When transporting with in the hospital, at least two people are required to move Infant Transport Incubator. Failure to use at least two people, could result in personnel injury or equipment damage.
- For safety, when raising or lowering the stand with an incubator in position, two person must support the full weight of the incubator. Do not unlock the latch unless the weight is fully supported. Personnel injury or equipment damage could occur.

3.14 Override

To enable override option of Skin mode in the Infant Transport Incubator, by selecting the enabling of override option (ON/OFF) next to set temperature in the set skin temperature display. The override temperature range from 37.6°C to 39°C.

3.15 Shut down Procedure

- Remove the baby from the mattress of Infant Transport Incubator.
- Ensure oxygen supply is stopped.
- Switch OFF the Infant Transport Incubator by the switch in the front panel.
- Switch OFF the white color main switch at the side of the Infant Transport Incubator when charging completed.

3.16 Accessories

3.16.1 Standard Accessories

#	Accessory Name	Single-use / Reusable	Part no.	Intended use	Picture
1.	Skin probe	Reusable	50-05-239	Intended to measure the skin temperature of patient	
2.	Mattress	Reusable	87-00-008	Intended for the placement of patient (baby)	

3.16.1 Optional Accessories

#	Accessory Name	Single-use / Reusable	Part no.	Intended use	Picture
1.	Suction Bottle	Reusable	30-05-068	Suction Bottle collect the secretion of fluids like mucous and phlegm during therapy.	

Section 4: Cleaning and Maintenance

- 4.1 General
- 4.2 Cleaning
- 4.3 Air Filter replacement
- 4.4 Lifetime of product
- 4.5 Lifetime of Silicone Heater
- 4.6 Replacement of spare and maintenance
- 4.7 Transport/Movement details

4.1 General

- Always switch off the equipment while cleaning
- This Section Provides Cleaning and Maintenance Instructions. Where necessary, disassembly instructions are provided.
- Routinely inspect patient compartment for signs of breakage and replace assemblies before placing Infant Transport Incubator into service.



Warning

- Make sure that the Oxygen supply to the Infant Transport Incubator is turned OFF and that the Transport Incubator is disconnected from the oxygen supply when performing cleaning and Maintenance procedures; a fire and explosion hazard exists when performing cleaning and/or Maintenance procedures in an oxygen administration.
- Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning
- Don't pour the water for cleaning it may enter into the electronics circuits it cause short circuit and get shock.
- Don't use flammable agents for cleaning even Small quantity of flammable agents such as ether and alcohol, left in the incubator it can cause fire in connection with oxygen.
- Disconnect power to the Infant Transport Incubator and allow the heater to cool before cleaning to avoid the possibility of a burn.



Caution

- Don't keep the metal surface in wet condition it may cause corrosion and damage the part
- Use the cleaning solution sparingly on a cloth when cleaning the Infant Transport Incubator. Do not saturate the unit – excessive solution causes damage to internal components.
- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

The service period for this equipment is six years.

4.1.1 Disassembly for cleaning

Note: For routine cleaning there is no need to separate the hood/Base assembly from the trolley. If Separation is necessary, refer to the installation section 2.

- Disconnect the Sensor cables from the Shell and slowly raise the hood.



Caution

- Before lifting Infant Transport Incubator Hood for cleaning, ensure that all mounted accessories have been removed to prevent possible interference with the raised hood.

1. Removal of Mattress Tray



Picture 42

- ❑ Open the Side panel, take the mattress, Press the stopper and pull the Mattress tray.

2. Removal of Access Door Gasket



Picture 43

- ❑ Remove Access door Gaskets from each side of the hood by pulling them free

3. Removal of Tubing Access Grommet



Picture 44

- ❑ Remove Tubing Access Grommets from each side of the hood by pulling them free.

4. Removal of Micro Filters



Picture 45

- ❑ Remove the Air intake Micro filter Cover by loosening the two thumbscrews.

5. Removal of Hood



Picture 46

- ❑ Unlock the hood and pull-up and take out from the shell.

- ❑ Remove Disposable Iris Entry Port Sleeves by pulling each Sleeve off the retainer rings. Wipe clean.

4.2 Cleaning

During cleaning the Infant Transport Incubator and its accessories, the processing shall comply with ISO 17664:2021 for reusable of the device

1. Clean the equipment with dampened cloth using soap (e.g. liquid dish soap) and clean water.
 2. Rinse the equipment completely with water dampened cloth.
 3. Disinfect the equipment by using 2% Glutaraldehyde to inactivate any remaining pathogens.
- ❑ When the equipment is not in use, all approachable external surfaces should be cleaned daily with an antiseptic solution like 2% glutaraldehyde. Every seventh day, after shifting the baby to another cot, the equipment should be cleaned thoroughly, first by mild detergent solution and then by antiseptic solution for **3 minutes**. All detachable assemblies, are to be treated similarly
4. Rinse with dampened cloth using sterile or clean water (i.e. water boiled for 5 minutes and cooled). Sterile water is preferred for rinsing off residual liquid chemical disinfectant from Infant Transport Incubator that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 µ filter).
 5. Dry Infant Transport Incubator using dry towel or cloth.



- It is recommended that when an infant is discharged, or at least once a week, to thoroughly clean and disinfect the Infant Transport Incubator. The most effective way to clean is to first disassemble in categories according to the method of cleaning required.
- Periodically clean and disinfect the incubator, else it may cause cross infection

4.2.1 Cleaning and Disinfection of Temperature Probe (Skin probe)

The cleaning methods listed below and do not affect the integrity or performance of the probe. It is the user's responsibility to qualify any deviations from these procedures, both for disinfecting efficacy and physical effect on the probe.

1. Physically clean the skin probe with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. When the equipment is not in use, temperature probe cable surfaces should be cleaned daily with an antiseptic solution like **2% glutaraldehyde** and leave for **3 minutes**.
3. Then rinse the temperature probe by wiping using water dampened cloth
4. Dry temperature probe using dry towel or cloth



- After every treatment, detach the temperature probe and clean thoroughly on the cable surface, first by light detergent solution and then by antiseptic solution for 3 minutes.
- Some Chemicals cleaning agents may be Conductive and/or leave a residue which may permit a built-up of dust or dirt which may be Conductive. Do not permit cleaning agents to contact electrical components. Do not spray cleaning Solutions onto any of these Surfaces.
- Don't keep the metal surface in wet condition it may cause corrosion and damage the part
- Do not apply cleaning solutions to the probe connector.

4.2.2 Cleaning and Disinfection of Access door gasket and Tubing access grommet

1. Physically clean the Access Door Gaskets and Tubing access grommets with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. Place the Access door gaskets and Tubing Access Ports into a Suitable container filled with 2%4 glutaraldehyde and leave for 3 minutes.
3. Then rinse the Access Door Gaskets and Tubing access grommets by wiping using water dampened cloth
4. Dry Access Door Gaskets and Tubing access grommets using dry towel or cloth



- Some Chemicals cleaning agents may be Conductive and/or leave a residue which may permit a built-up of dust or dirt which may be Conductive. Do not permit cleaning agents to contact electrical components. Do not spray cleaning Solutions onto any of these Surfaces.
- Don't keep the metal surface in wet condition it may cause corrosion and damage the part

4.2.3 Cleaning and Disinfection of Controller, Shell and Trolley

1. Physically clean the Controller, shell and Trolley with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. Rinse the Controller, shell and Trolley with water damped cloth.
3. Disinfect the Controller, shell and Trolley by using 2% Glutaraldehyde to inactivate any remaining pathogens and leave it for 3 minutes.
4. Then rinse the Controller, shell and Trolley by wiping using water damped cloth
5. Dry Controller, shell and Trolley using dry towel or cloth



- When cleaning the interior of the Infant Transport Incubator shell, care must be taken to prevent liquids from entering the motor shaft opening.

4.2.4 Cleaning and Disinfection of Hood and Inner walls

The Inner walls are hinged on the access Panel(s) or rear Wall of the transport incubator. Refer to figure and release the inner Wall by pressing on the catches located at the top of the inner wall

1. Physically clean the Inner wall and access doors with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. Rinse the inner wall and access doors with water damped cloth.
3. Disinfect the inner wall and access doors by using 2% Glutaraldehyde to inactivate any remaining pathogens and leave it for 3 minutes.
4. Then rinse the inner wall and access doors by wiping using water damped cloth
5. Dry inner wall and access doors using dry towel or cloth

4.2.5 Cleaning and Disinfection of Heat sink and Fan impeller

1. Physically clean the Heat sink and Fan impeller with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. Rinse the Heat sink and Fan impeller with water.
3. Disinfect the Heat sink and Fan impeller by using 2% Glutaraldehyde to inactivate any remaining pathogens and leave it for 3 minutes.
4. Then rinse the Heater radiator and Fan impeller by wiping using water damped cloth
5. Dry inner wall and access doors using dry towel or cloth.

4.2.6 Cleaning and Disinfection of Mattress tray and Heater/Impeller cover

1. Physically clean the Mattress tray and Heater/Impeller cover with soft cloth, removing all visible contaminants by wiping using water general cleaning.

2. Rinse the Mattress tray and Heater/Impeller cover with water damped cloth.
3. Disinfect the Mattress tray and Heater/Impeller cover by using 2% Glutaraldehyde to inactivate any remaining pathogens and leave it for 3 minutes.
4. Then rinse the Mattress tray and Heater/Impeller cover by wiping using water damped cloth
5. Dry Mattress tray and Heater/Impeller cover using dry towel or cloth



Caution

- Alcohol can cause crazing of the Clear Acrylic hood. Do not Use alcohol for Cleaning.
- Do not expose the Hood assembly to direct radiation from germicidal lamps. Ultra violet radiation from these sources can cause cracking of gaskets, fading of paint, and crazing of the Clear Acrylic hood.
- Failure to clean could result in sufficient lint built-up to reduce air flow, which will affect temperature control and cause high oxygen concentrations.

4.2.7 Reassembly after cleaning

Note: Inspect all cleaned components for any breakage or cracks before reassembling into the Infant Transport Incubator. Harsh cleaning agents may attack some of the plastics used in the Patient Compartment.

- Install the Heat sink and Fan Impeller.
- Install the Mattress Tray.
- Install the Disposable Mattress cover. Place a new disposable mattress cover over the mattress, and then place the mattress onto the tray.
- Install Disposable Iris Entry Port Sleeves
- Install a new Iris Port Sleeve as Shown in figure
- Install tubing access Ports into the front and rear edges of each side of the hood. Replace if distorted or torn.
- Install an Access Door gasket on each Access Door.
- Install a New Access Door Cuff onto each Access Door gasket by stretching the larger diameter elastic band into the groove in the gasket. When installed correctly, the cuff has a small opening at its center. The Access door latch with slight pressure and should open when the latch lever is de-pressed.
- Install a new Air Intake Micro filter if necessary (Discolored or dirty). Replace the Air Intake Micro filter Cover and tightens the two thumbscrews.

Important: Perform a complete functional checkout (Refer 2.5) before returning the unit to service.



Caution

- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

4.3 Air filter replacement

A dirty Inlet filter may affect oxygen Concentration and/or cause carbon dioxide built-up. Be sure the filter is checked on an every 15 days commensurate with local conditions. Particularly, if the incubator is used in an unusually dusty environment, more frequent replacements may be necessary.

4.4 Lifetime of product

Since the product is classified under programmable medical electrical system and in case of unavailability of microcontroller the life time of the product can be considered as five years and Service life of the device is extendable up to 1 years considering the replacement of spares and faulty components. So, the service life of the device is six years (5 years of lifetime + 1 year service life).

4.5 Life time of Silicon Heater

The life time of the Silicon Heater is three years, after which it should be replaced.

4.6 Replacement of spare and Maintenance



Warning

- Replacement of detachable parts and interchangeable parts such as battery, PCB, power cord, heater, fan, etc., should be replaced only by the trained service personnel.

4.6.1 Disassemble Hood assembly

When cleaning the hood, disassemble it by removing the detachable components and lift the hood assembly from the shell assembly.



Picture 47

Hood assembly can be removed by unlocking the quick clamps provided on its sides and hood can be lift it-up and take out from the shell and kept it safely on a suitable table. It consists of four major parts, Hood, Front access panel, side access panel LH, RH. These panels are insulated circumferentially with gaskets on its edges to control air temperature, and leakages.



Picture 48

4.6.3 Control system



Picture 49

4.6.4 Replacement of Battery



Picture 50

- Unscrew and pull out the battery compartment, after removing the bracket assembly.
- Unscrew the nut in the terminals with suitable spanner, and replace the new batteries, ensure the right polarity of the terminal connections.

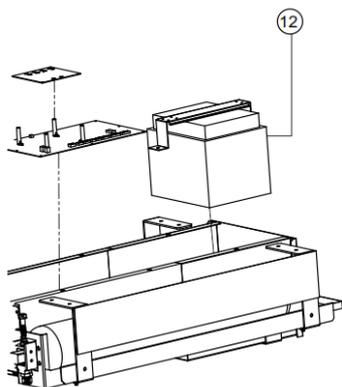


Figure 4

- Battery can be removed by unscrewing the battery clamp

4.6.5 Oxygen Cylinder removal



Picture 51

- Unscrew the bolt and clip to remove the empty cylinder from the bracket and replace the new cylinder and tighten again.
- Ensure the cylinder neck should be opposite side of the battery compartment panel.

4.6.6 Disassemble the shell & Hood from the trolley base



Picture 52

- By unscrewing the bolts from the trolley frame we can detach baby incubator from assembled trolley.

4.7 Transport/Movement details

When transporting the Infant Transport Incubator,

- Remove the baby from the mattress.
- Remove the IV bottle from the IV pole.
- Remove the equipment if exists in the mayo tray.
- Drain the water from the chamber as per drain procedure.
- Release all brakes then move safely.

Section 5: Specification

Control mode	Servo skin, Servo air, Standby
AC Voltage supply	~230V/50Hz
External Battery Supply	12V, 16A
Battery capacity	12V, 42Ah
Power Rating	220W Max.
Heater Power Rating	175W Max.
Circuit breaker	20A/250V
Observation lamp	8W, 10V
Performance Characteristics	
Temperature rise time	11° C @ 45 minutes
Temperature variability	≤1.0° C
Temperature overshoot	≤2.0° C
Temperature uniformity	≤1.5° C
Air Filter	Removes >99% airborne particles greater than 0.5 micron diameter
Controller Displays	
Battery condition status	Display shows the indication of battery as bar (25%, 50%, 75% and 100%).
Power mode	Illuminates AC, DC and Battery.
Heater power	Display shows the indication of heater output percentage (10%-100%).
Skin temperature °C	Displays infant's skin temperature
Air temperature °C	Displays infant's air temperature
Air set temperature range	23 to 39° C
Skin set temperature range	30 to 37.5° C, override 37.6 to 39° C
Carbon di oxide (CO ₂) level within the hood	Less than 0.8% when a mixture of CO ₂ in air is delivered at 750 ml/min at a point 10cm above the center of mattress
Sensor	Thermistor
Air velocity over the bed	<0.3 m/sec
Noise level inside incubator	<60 dB
Air Probe	Accuracy 0.2° C
Skin Probe	Accuracy 0.2° C
Thermostat	90 ± 5° C, Manual reset, normally closed
Display Resolution	0.1° C
Alarm Indication	
Skin Temperature High	If skin temperature is > 1° C from set temp.
Skin Temperature Low	If skin temperature is < 1° C from set temp.
Air Temperature High	If air temperature is > 1° C from set temp.
Air Temperature Low	If air temperature is < 3° C from set temp.
Air Sensor Disconnect	If air probe is removed or damaged

Skin Sensor Disconnect	If skin probe is removed or damaged
Skin Sensor Fault	If skin sensor is short or fails to sense
Over Temperature	If skin/air temperature is >39°C in any mode
Heater Fault	If the heater is disconnected or fails
Heater sensor fault	Heat sensor gets disconnected or fails
Battery Sensor fault	Battery sensor gets disconnected or fails
Battery Over Temperature	Battery temperature reaches to a high limit 78.0 deg C and above
Fan fault	If the fan is disconnected or fails
Oxygen sensor Disconnect	Oxygen probe sensor gets disconnected or fails
Humidity sensor Disconnect	Humidity sensor gets disconnected
Air flow fail	Air flow temperature reaches to a high limit 80.0 deg C and above
Power Fail	If the power supply is disconnected or fails
Timed Acknowledged key	15 minutes
Algorithm of the alarm	
High Priority	975 Hz tone, 10 Pulse burst, Pulse spacing: 0.1s, 0.1s, 0.3s, 0.1s, 0.5s, 0.1s, 0.1s, 0.3s, 0.1s repeat time: 2.5s
Medium Priority	975 Hz tone, 3 Pulse burst, Pulse spacing: 0.2s, 0.2s repeat time: 7.5s
Low Priority	975 Hz tone, 2 Pulse burst, Pulse spacing: 0.2s, repeat time: 7.5s
Sound Pressure Level	
High priority alarm	72 dB
Medium priority alarm	68 dB
Low priority alarm	66 dB
Battery Specifications	
Battery	12 VDC, 42AH, rechargeable (Sealed Lead Acid)
Battery Backup*	8 hours on 100% battery level (*Test condition: Air mode, 32°C Set point, 23°C ambient)
Life expectancy	200 complete charge/discharge cycles
Minimum charge time	Minimum 8 hours or until charging indicator LED's blinking
Battery shut down voltage	<10.5V
Standard Features	
Access doors	2 nos.
Cylinder mounting provision	2 nos. A type
Trolley	Collapsible Stainless Steel
Optional Features	
External DC Input Cable	Optional

Battery Charging Power Supply (SMPS)	
Input	100-240 VAC, 50/60 Hz, 300 VA
Output	15 VDC, 20 A
MDD/MDR Product Classification	Class II b
IEC 60601-1 Specifications	
Type of Protection against electric Shock	Class 1
Degree of Protection against electric Shock	Type BF (Skin Probe), Type B (mattress), Type B (Bed Strap)
Mode of Operation	Continuous
Protection against hazardous of explosion	Not protected
Protection against increase of liquid	Not protected
Quality Standard Adherence	
Quality Management System	ISO 13485:2016
Electrical Safety Standard	IEC 60601-1
Particular Product Standard	IEC 60601-2-20
Emergency Medical Service	IEC 60601-1-12
Alarm standard	IEC 60601-1-8
EMC Safety Standard	IEC 60601-1-2
Graphical Symbols	ISO 15223
Environment Operating Conditions	
Temperature range	15°C to 35 °C
Humidity range	15 – 90% RH, non-condensing
Altitude	Sea level to 1.9 miles (3Kms)
Atmospheric Pressure	50 – 106 kPa
Transport and Storage conditions	
Temperature range	-10°C to 60 °C
Humidity range	50% - 90% RH, non-condensing
Physical Dimensions	
Equipment Dimensions	160 cm (H) x 60 cm (W) x 124 cm (L)
Dimensions of bed	63.5cm (L)x 31.7cm(W)x 2.5cm (TK)
Weight	115 kgs
Castors	5" double castor (4 lock wheels)
IV Pole Max. Load	1.5 Kg
Mattress Load	5 Kg
Suction	2.5 Kg
Auxiliary tray Load	3 Kg

Section 6: Warranty

6.1 Conditions

1. The warranty is confined to the first purchaser of the product only and is not transferrable.
2. Repairs under warranty period shall be carried out by the company authorized personnel only
3. In the event of repairs of any part/s of the unit, this warranty will thereafter continue and remain in force only for the unexpired period of the warranty. The time taken for repair and in transit whether under the warranty or otherwise shall not be excluded from the warranty period.
4. In case of any damage to the product/misuse detected by the Authorized service personnel the warranty conditions are not applicable and repairs will be done subject to availability of parts and on a chargeable basis only
5. Wear and Tear, and defects caused by manipulation or unsuitable treatment are not included under the warranty.
6. Temperature Probe & Battery carry only 3 months warranty. Lamps do not carry any warranty.
7. We warranty this unit for 12 months from the date of Installation. Warranty includes the repair and replacement of faulty components.
8. Defects caused by improper use, and defects due to causes beyond control like lightning, abnormal voltage, acts of god, and also defects caused by rats, cockroaches or any other insects will not be covered under warranty.
9. Warranty is not applicable if the equipment is not purchased from Neötech/authorized Neötech Dealer
10. Warranty is not applicable if the warranty card is not filled and sent back to Neötech.
11. Life time of the product is five years and Service life of the device is extendable up to 1 years so, the service life of the device is six years (5 years of lifetime + 1 year service life).

Customer Details cum Warranty Card

Date: _____

Hospital Name & Address: _____

Contact Person & Telephone/Fax No _____

Email _____

Department: NICU / PICU / OT / Gynecology / Causality / Others _____

Equipment Name: _____

Model No: _____ Sl. No. _____

Date of Purchase: _____ Date of Installation _____

Name of Authorized Dealer: _____

Customer Signature & Date
(I accept the terms & conditions of Warranty)

Dealer Signature with seal

Kindly fill the above and send the same

To:
The Service In-charge
nice Neötech Medical Systems Pvt. Ltd.
No. 85-86, Krishna Industrial Estate,
Mettukuppam, Vanagaram,
Chennai-600095. Tamil Nadu, INDIA
Ph: 91-44-24762594, 24764608
Tele Fax: 91-44-24766920 – Ext: 203
Email: service@niceneotech.com, info@niceneotech.com
Web: www.niceneotech.com
Toll Free No. 1800-425-2594 (India only)

From _____

Section 7: Trouble Shooting

- 7.1 General System Failure
- 7.2 System Fault Infant Transport Incubator
- 7.3 Maintenance Intervals
- 7.4 Disposing of the Unit

7.1 General System Failure

Sl. No.	Problem	Cause	Remedy
1.	Power failure LED is ON with audio indication	Power Failure	Check the unit is Plugged in to Main supply
			Check the mains are switched ON.
			Check External Battery supply
			Otherwise Contact nice Neotech

7.2 System Fault Infant Transport Incubator

Sl. No.	Problems	Possible Causes and Remedy
1	No Display on the Control Panel	Check A/C Supply Voltage
		Check if Power Cord is disconnected
		Check circuit breaker
		Otherwise, Contact nice Neotech
2	No Heater Output	Check the relay and circuit breaker.
		Set Temperature may be less than Actual Temperature
		Check Heater Connection
		Otherwise Contact nice Neotech
3	Equipment Working But Fan & Heater output not working	Check the Fan connection
		Check Fuse in the PCB.
		Check Transformer Voltage
		Replace Fan.
		Otherwise Contact nice Neotech.
4	Equipment not give the Audio Indication	Check the Temperature it may near to the Set temperature
		Check Mute ON.
		Check Speaker connection
		Otherwise Contact nice Neotech
5	Patient Temperature Display shows "Skin sensor disconnect" with Continuous Indication (Skin sensor disconnect: Sensor Open)	Check if skin Probe is Disconnected from the equipment.
		If skin probe is defective, replace new probe
		Otherwise Contact nice Neotech
6	Air Temperature Display shows "Air sensor disconnect" with Continuous Indication (Air sensor disconnect: Sensor Open)	Check if air Probe is Disconnected from the equipment.
		If air probe is defective, replace new probe
		Otherwise Contact nice Neotech
7	Display shows "Heater Fault"	Check the relay and fuse.
		Check Heater Connection
		Otherwise Contact nice Neotech
	Display shows "Fan Fault"	Check the Fan.
		Check Fan Connection
Otherwise Contact nice Neotech		
8	Over temperature Indication i.e. Temp. > 39 ° C	Check Infant Transport Incubator Temperature above 39° C
		Check the infant's skin.
		Check the skin probe intact.
		Check Infant Fever
9	Continuous Skin Temperature High Indication	Check Patient Temperature is 1°C above Set Temperature
		Check the Infant Transport Incubator temperature
		Otherwise Contact nice Neotech

10	Continuous Skin Temperature Low Indication	Check Patient Temperature is 1°C below Set Temperature
		Probe may be wet. Otherwise Contact nice Neotech
11	Continuous Air Temperature High Indication	Check Hood Temperature is 1°C above Set Temperature
		Otherwise Contact nice Neotech
12	Continuous Air Temperature Low Indication	Check Infant Transport Incubator Temperature is 3°C below Set Temperature
		Probe may be wet.
		Otherwise Contact nice Neotech
15	Oxygen sensor Disconnect	Check the Oxygen probe sensor disconnect
16	Humidity sensor Disconnect	Check the Humidity sensor disconnect
17	Air flow fail	Air flow temperature reaches to a high limit
18	Power Fail	If the power supply is disconnected or fails
19	Heater sensor fault	Heat sensor gets disconnected or fails
		Air Flow Sensor gets disconnected or fails
20	Infant Transport Incubator Temperature over Mattress does not rise	Check Low Infant Transport Incubator Temperature it should be approximately (22-30°C)
		Check draft around air conditioning outlet
		Low Supply Voltage
		Otherwise Contact nice Neotech
21	Infant Transport Incubator Temperature over Mattress rises excessively	Check direct Sun light, Heating Device or other Heat Source
		Otherwise Contact nice Neotech
22	Infant Transport Incubator Temperature over Mattress dose not stabilize	Check unstable ambient temperature (should be 22-30°C)
		Check Strong Air conditioning draft
23	Temperature Display does not display Infant's Temperature accurately	Probe Thermal Sensitive Portion attached improperly
		Check Thermal Sensitive Portion of Probe covered improperly
24	Baby skin Temperature not correlate with display Temperature	Check sensitive portion of the Probe is fixed with baby skin properly.
		Check Probe is fixed to the lower abdomen of baby
25	In Skin Mode Baby getting over heat but machine gives Low Temperature indication	Check the probe is intact with lower abdomen of baby
		Check the probe is removed and keep away
		Check the Set Temperature is high
26	Infant Transport Incubator temperature is not maintained	Check the Access panel, it should be closed
		Check the Access Port, it should be closed
		Check the Iris Port, it should be closed
		Check the environment temperature , it should be >22°C

7.3 Maintenance Intervals

- Always disinfect and clean the unit and accessories before any maintenance – even when returning the unit to the supplier for repair.
- Always turn off and disconnect power supply of the machine before any maintenance.
- Use only nice Neotech's original parts for maintenance.



Warning

- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- Don't misalign the EMI Shielding and the beads it may cause the EMI interference to the equipment.
- **Access Panel:** To visually inspect the panels every day, whether it is properly fixed or breakages or lose.

- **Temperature measuring system:** Measuring system should be checked by trained service personnel with calibrated test probe every year.

Measurements Specific to units:

- Place Measuring stand with calibrated precision thermometer/calibrated temperature monitor at the centre of mattress and clamp skin sensor under the holding spring on the top of the Measurement Stand at above 10 cm of the Mattress
- Set the set-temperature of 32°C (Air mode).
- Raise set-temperature to 36°C and after at least 30 mins. Again note the indicated ACTUAL air temperature and the ACTUAL temperature.
- The ACTUAL VALUE indicated may deviate by $\pm 0.2^{\circ}\text{C}$ from the set -temperature. If this deviation is exceeded, the dynamic adjustment must be performed by a qualified technician according to the service Instructions.
- On the nice 3000 over-temperature of the monitoring temperature sensor is detected. The indication threshold for this is defined by the software at 39°C. No adjustment is therefore necessary if the conditions in points 2 and 4 are satisfied.
- Air flow fails indication: Infant Transport Incubator with setting 36°C. Remove the fan impeller and wait for 30 minutes. The “air flow fail indication” must be given.
- The safety check results should be recorded.
- If the unit is not functionally and/or operationally reliable, it must be repaired or the operator informed of the danger arising from the use of the unit.

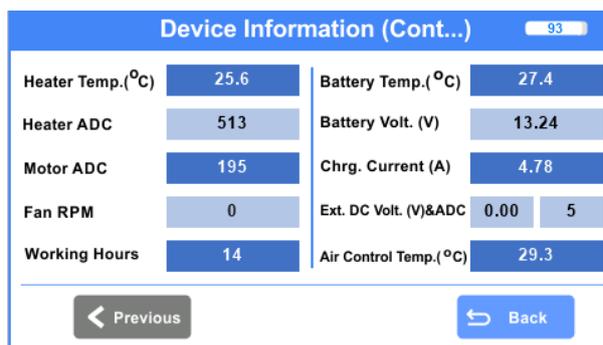
Note: No need of calibration if a new temperature probe is replaced.

- **Inspection & Maintenance:** Yearly by trained Service Personnel.

Safety Checks:

Note: The following must be performed on this unit at least every 6 months by persons who are capable of carrying out these safety tests in a proper way on the basis of their training. Knowledge and practical experience and who do not have to be instructed in this work.

- Visual checks of the unit and accessories for mechanical damage affecting functions
- **Acrylic Hood** Check secure Access port by pressing from inside. In the event of wear, replace the Access port. Re-adjust turn bolt of hinge if play, present.
- Check Blower (fan), heater, air flow Sensor, air sensor and skin Sensor.
- **Fan Motor:** Noise must be Barely Audible on the bed (noise level < 50 dB) Replace motor if bearings damaged.
- **Skin Temperature Sensor:** Check line for damage and loose contacts.
- Check Safety Warning notices for 'Legibility'.
- Check equipment fuse links for rated current and fusing characteristic.
- Perform functional check according to operating instructions (section 3)



Click the Setting icon, then navigate to Device info, a new window displays Device information. The Device Information displays details of machine in the Present state.

7.4 Disposing of the Unit

- At the end of its Service life Dispose of the equipment in accordance with National waste Disposal Regulation or ask a suitable Disposal contractor to dispose of the unit. The local Environmental agency can supply further details.



Caution

- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

Section 8: Spare Parts List

Sl. No.	Part No.	Part Name	Qty	UOM
1	30-05-106	nice 3000 Control PCB Assembly	1	No
2	30-05-161	PCB nice 3000 Charger PCB Assembly	1	No
3	30-05-148	PCB – nice 3000 LED PCB Assembly	1	No
4	91-00-244	Sealed Lead-Acid Battery 12V 42AH	1	No
5	30-05-163	Auxillary Tray and Blue Belt	1	No
6	30-05-158	nice 3000 - Air Flow Sensor Assembly	1	No
7	50-05-239	Skin Probe Assembly - nice 5100	1	No
8	30-05-152	nice 3000 - Hood assembly	1	No
9	30-05-159	observation lamp assembly	1	No
10	87-00-008	Mattress - nice 3000	1	No
11	76-00-115	Air Intake Filter - Transport Incubator	10	Nos
12	90-00-100	Power Cord Open Type 16A	1	No
13	93-00-040	Castor with Brake	4	Nos
14	91-00-197	Motor 42MM Brushless DC Fan	1	No
15	91-00-207	SMPS -RPS-300-15	1	No
16	91-00-173	Fan 80X80X25 – 12 VDC/0.5 W	1	No
17	91-00-051	Battery 9V Unchangeable	1	No
18	89-05-029	Display-NX4827P043-011C (4.3 inch Capacitive Touchscreen without enclosure	1	No
19	91-00-160	Circuit Breaker - 20A	1	No
20	88-00-161	O2 Cylinder (Optional)	1	No
21	88-00-164	O2 Flow Regulator (Optional)	1	No
22	93-00-038	Castor without Brake	1	No
23	30-05-063	Mattress Tray Assembly	1	No
24	30-05-164	IV Pole Assembly	1	No
25	30-10-089	Ventilator Pole	1	No
26	87-00-138	Humidity Sponge	1	No

Section 9: Manufacturer's EMC Declaration.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Infant Transport Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Transport Incubator should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class A	The Infant Transport Incubator is suitable for use in Professional and Hospital environment
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Infant Transport Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Transport Incubator should assure that it is used in such an environment.			
Emission test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Criteria C	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient. IEC 61000-4-4	± 2 kV for power supply lines	Criteria A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) 12 VDC power port	Criteria A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	70% dips for 25 cycles 0% of dips for 0.5 & 1.0 cycle 0% short interruption for 250 cycles	Criteria A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Infant Transport Incubator requires continued operation during power mains interruptions, it is recommended that the Infant Transport Incubator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Criteria A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Infant Transport Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Transport Incubator should assure that it is used in such an environment.

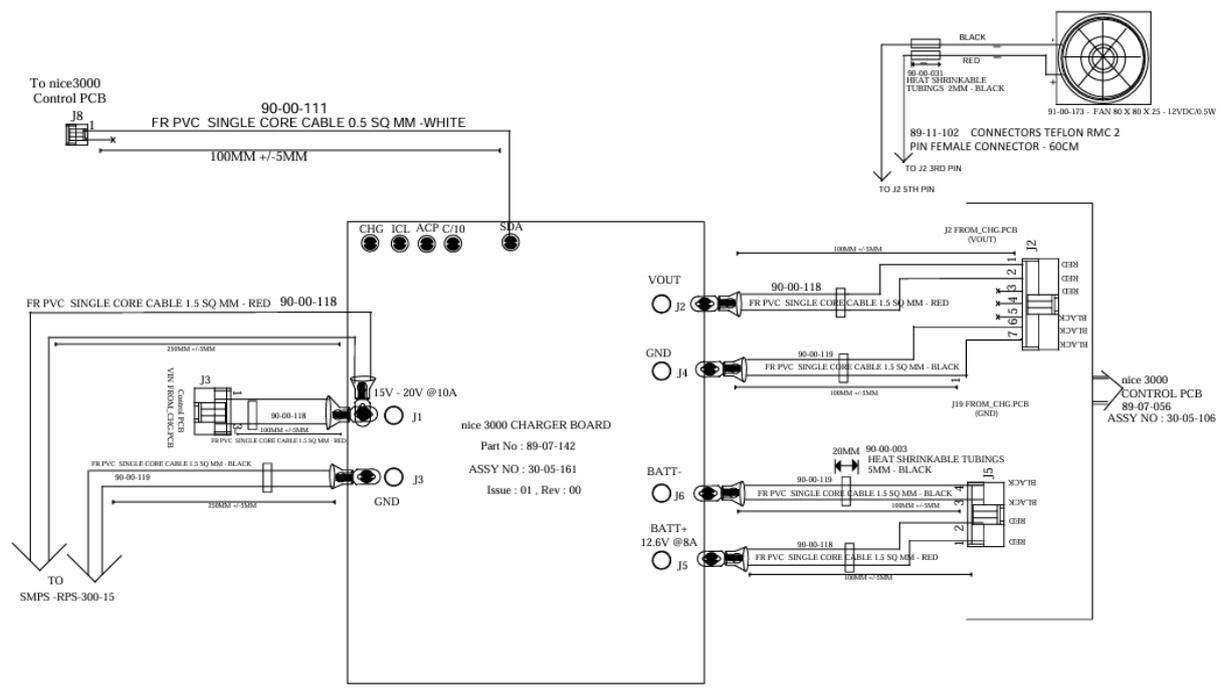
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands 10 Vrms 150 kHz to 80 MHz in ISM bands	Criteria A	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	Criteria A	

NOTE UT is the a.c. mains voltage prior to application of the test level.

Acceptance criteria:

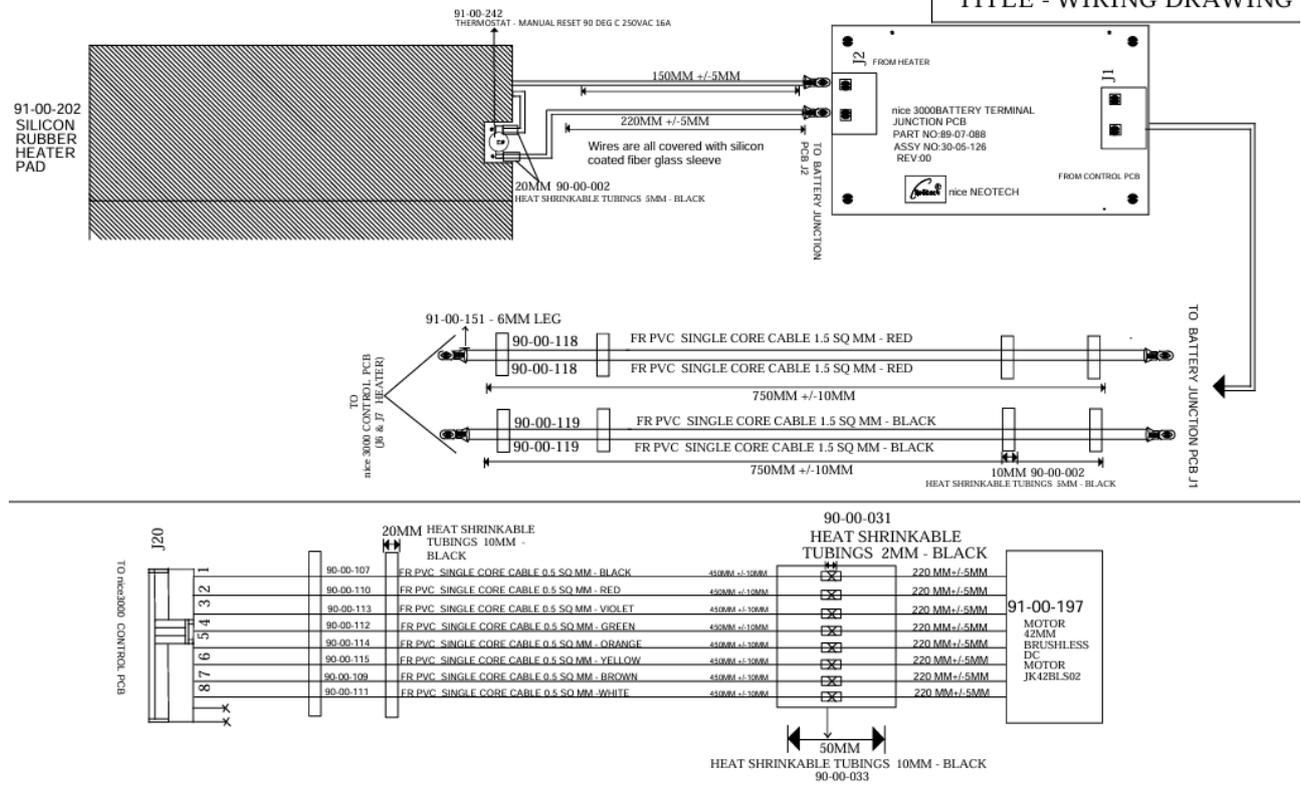
Performance criteria	Description
A	Normal performance within limits specified by nice Neötech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C	Temporary loss of function or degradation of performance, the correction of which requires operator intervention
D	Loss of function or degradation, which is not recoverable, owing damage to hardware or software, or loss of data

TITLE - WIRING DRAWING



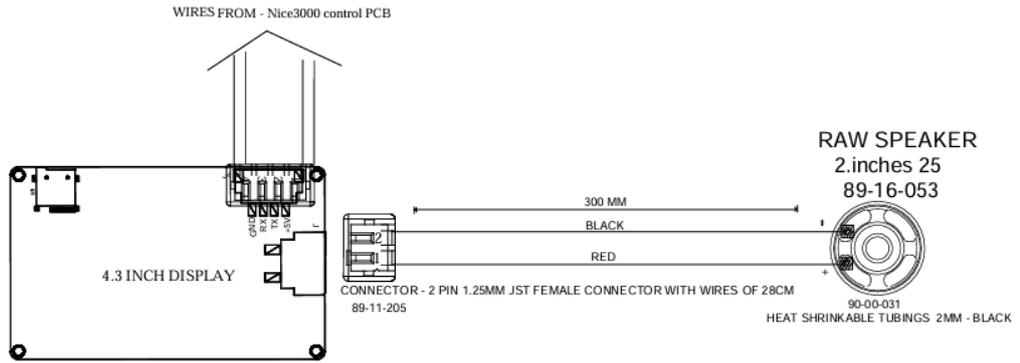
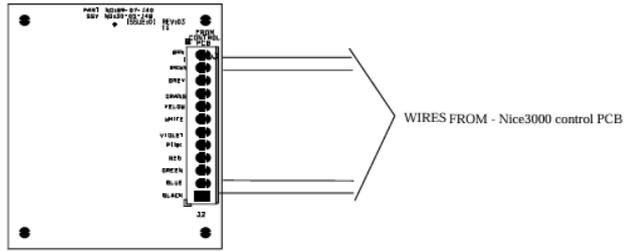
nice 3000 - Power Supply Assembly

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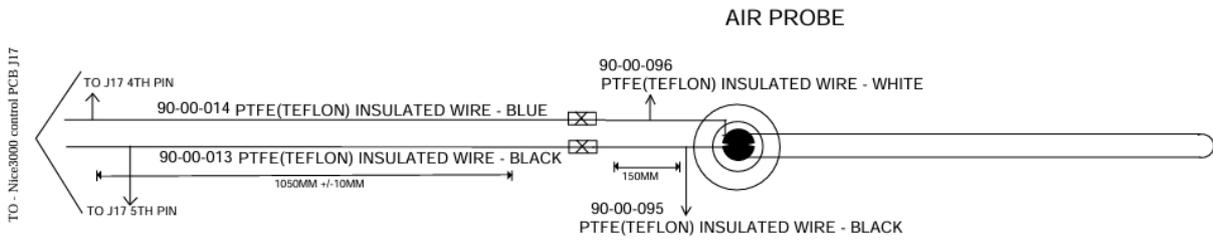
nice 3000 - Shell Assembly

TITLE - WIRING DRAWING



nice 3000- Front Panel Assembly

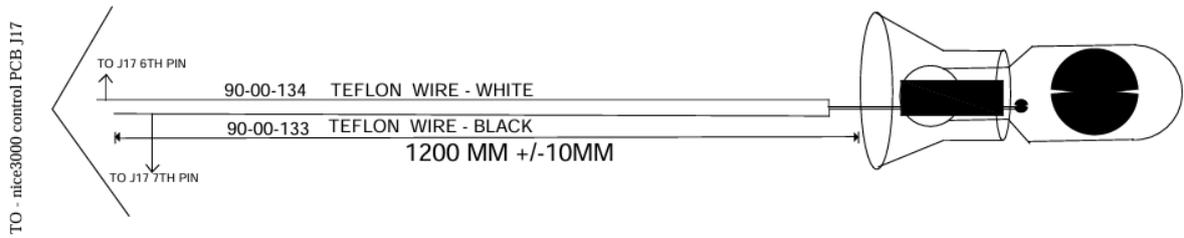
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nice 3000 – Air Probe Assembly

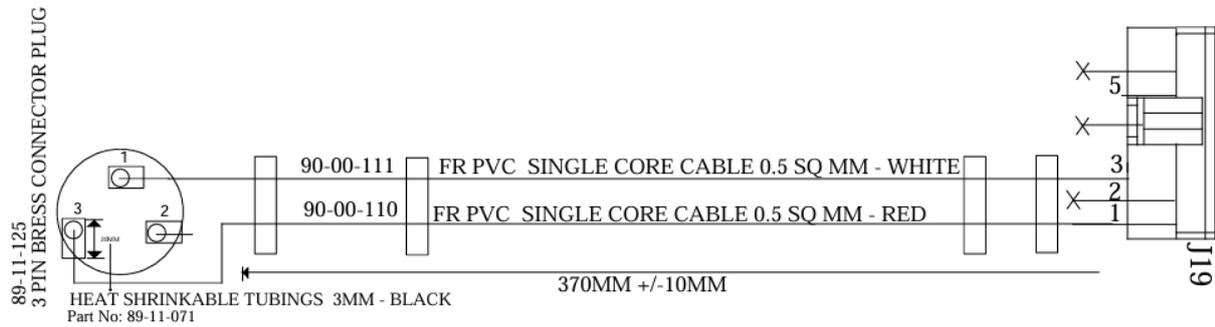
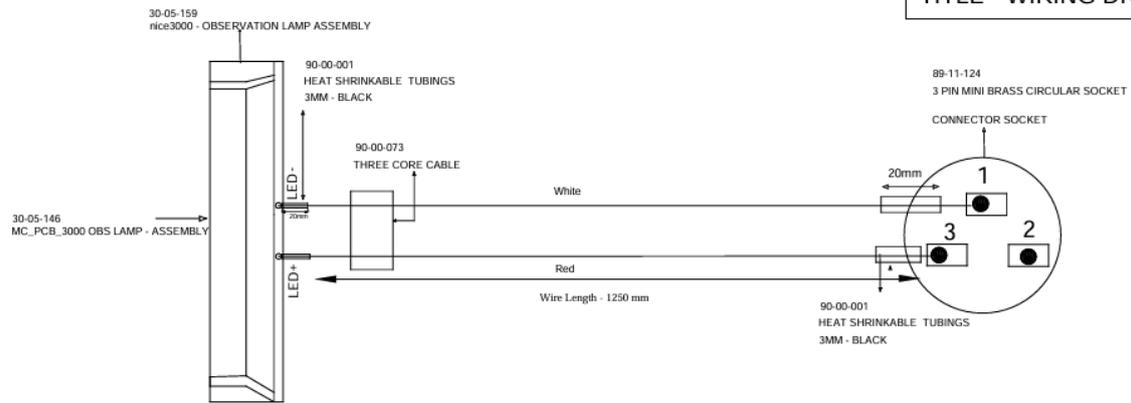
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AIR FLOW TEMP SENSOR



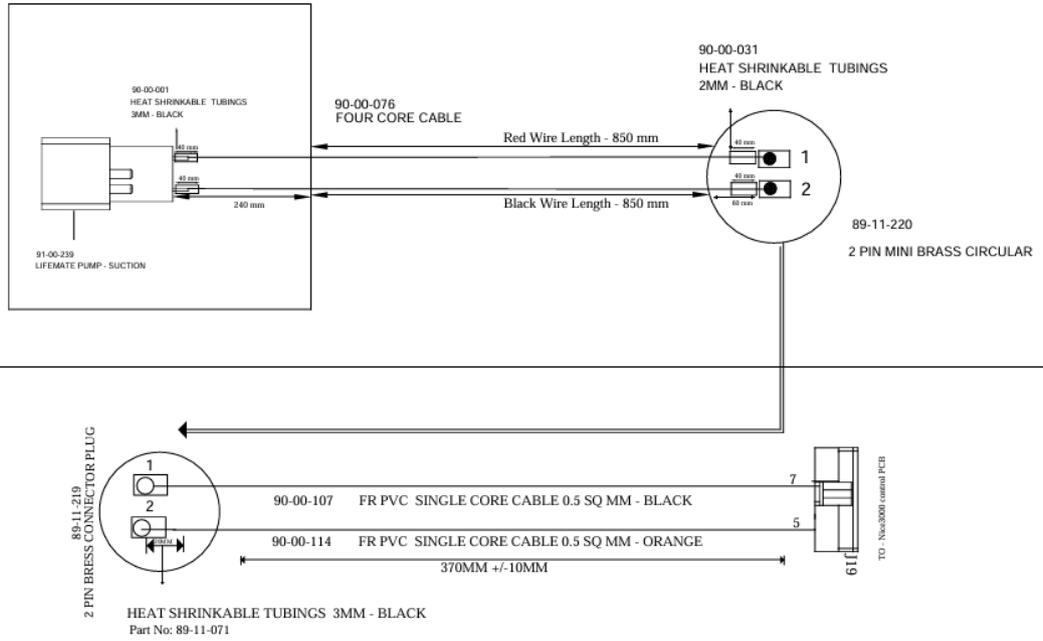
nice 3000 – Air Flow Sensor Assembly

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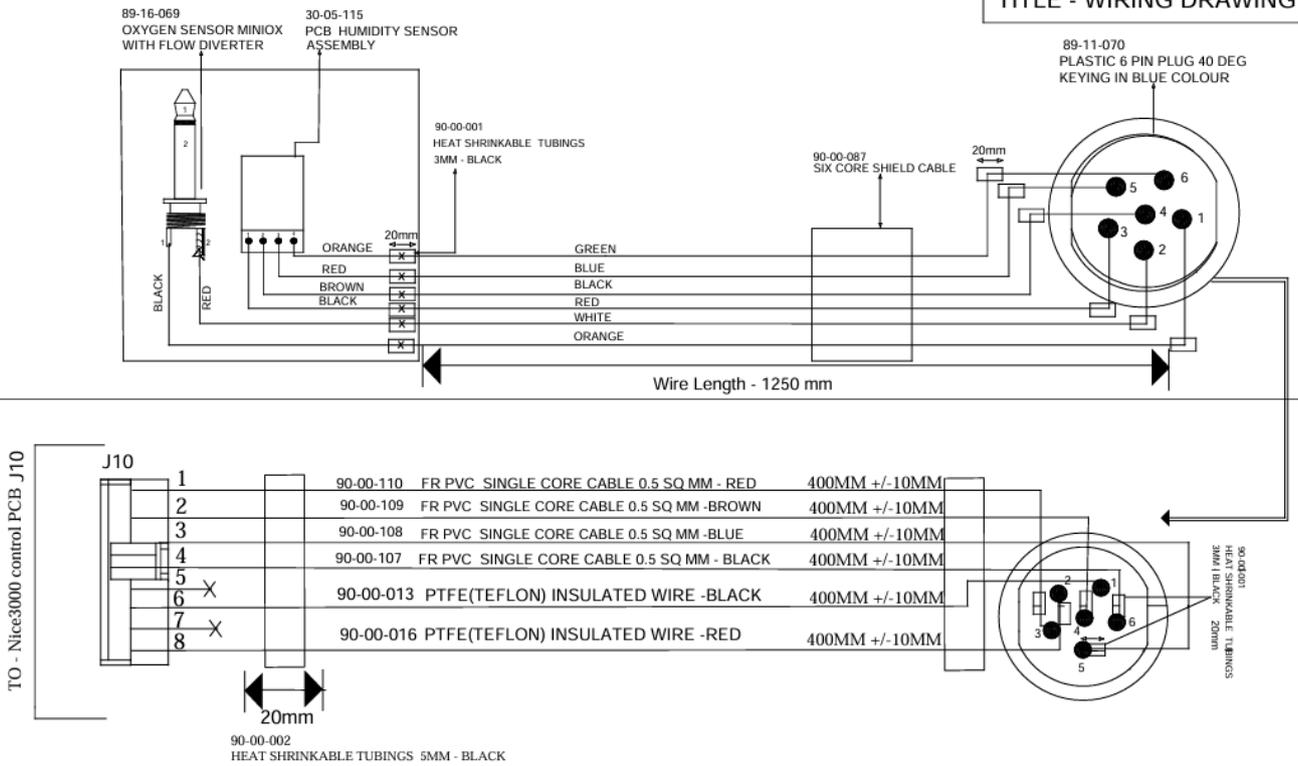
nice3000 Observation Lamp Assembly

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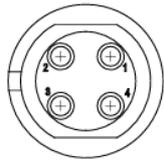


Suction Module Assembly

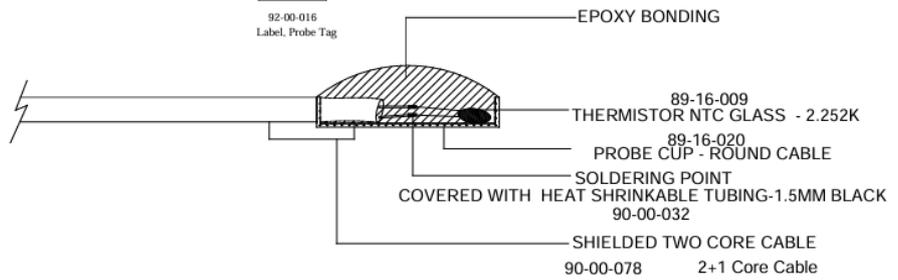
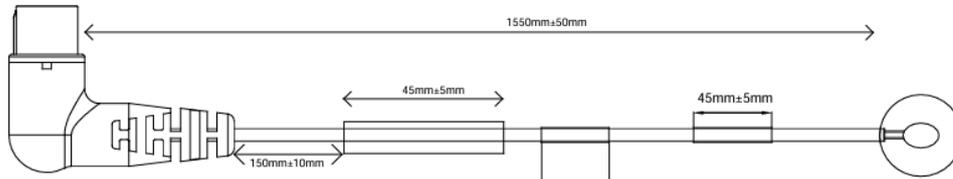
TITLE - WIRING DRAWING



nice 3000 – O2 and Humidity Sensor Assembly

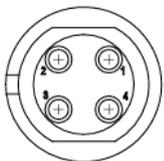


TITLE - PROBE DRAWING

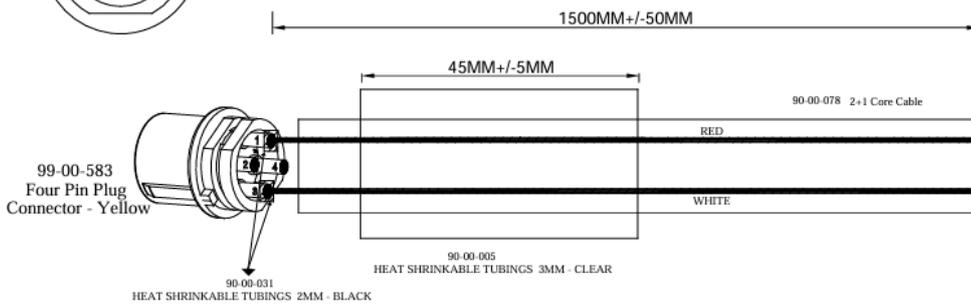


Skin Probe assembly nice 5000

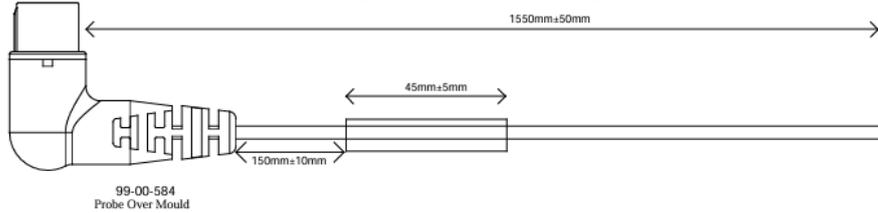
TITLE - PROBE DRAWING



Stage 1 Soldering



Stage 2 Moulding



Skin Probe Four Pin Plug connector Assembly

Section 11: Servicing Procedures



Warning

- Consult the manufacturer for repair and replacement of components. Spare parts are replaced only by the trained service personnel.

Precautions:

- ❖ Even if the infant transport incubator is switched off with the side panel switch, the unit is still energized. Disconnect the battery positive terminal before servicing.
- ❖ After servicing the infant transport incubator should be performance tested to ensure correct operation.
- ❖ Ensure the case screws are correctly fitted to the product after assembly.



Caution

- The infant transport incubator contains electrostatically sensitive components. Ensure antistatic procedures are followed when servicing.

1. Removing the PCB, Ensure mains plug has been disconnected from the wall socket and disconnect the battery positive terminal before servicing. Open the case and remove the PCB.
2. Ensure the correct type and rating fuses before replacing, Fuse ratings mentioned in section 5.
3. Before replacing the Heater, allow it to cool before attempting to replace.

Section 12: For Complaints/Adverse Events/Comments/Feedback

		Date:		
Hospital Name & Address:				
Contact Person & Contact No. & Email:				
Department:		NICU / PICU / OT / Casualty / Others _____		
Equipment name:				Model no.:
UDI / Serial No.:		Date of purchase:		Date of Installation:
Pick one:	<input type="checkbox"/> Complaints <input type="checkbox"/> Adverse Events <input type="checkbox"/> Comments <input type="checkbox"/> Feedback			

In case of adverse events, fill the below details:

Incident happened to: (Patient / User)	
Details of incident happened person: (Name/Age/type of incident)	
Severity of the event (Minor injury / Major injury / Death)	
Brief description of the event	

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

To:
 The Marketing In-charge
 nice Neotech Medical Systems Pvt. Ltd.
 No, 85-86. Krishna Industrial Estate,
 Mettukuppam, Vanagaram,
 Chennai-600095. Tamil Nadu,
 INDIA.
 Ph: 91-44-24762594, 24764608
 Email: marketing@niceneotech.com
 Toll Free No. 1800-425-2594 (India only)

NOTE: In case of serious/adverse events, report the incident to nice Neotech, European Authorized Representative and the competent authority of the Member State by filling and sending the below form as letter post or email.

Service Contact	EU Authorized Representative	Competent Authority
<p>nice Neötech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-600095. Tamil Nadu, INDIA. Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594 E-mail: service@niceneotech.com /info@niceneotech.com Web: www.niceneotech.com</p>	<p>Amstermed B.V Located in Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Mr. Mike Vermin Tel: +31 23 565 6337 info@amstermed.nl www.amstermed.nl SRN: NL-AR-000001971</p>	<p>Ministerie van Volksgezondheid, Welzijn en Sport Address:P.O. Box, 20350, The Hague, Netherlands Country:Netherlands Email: medicaldevices@minvws.nl Tel:+31 70 340 79 11</p>

Section 13: EC certificate Notified Body

Name:

PCBC – POLSKIE CENTRUM BADAN I CERTYFIKACJI

Notified body number:

1434

Address:

02-844 Warsaw,
469 Pulawska Street,
Poland.

Ph: +48 22 46 45 200
email: pcbc@pcbc.gov.pl